Policy Replaced with LCD L34434 Effective February 26, 2018

BlueCross BlueShield of Alabama

Name of Blue Advantage Policy:
Magnetic Esophageal Ring to Treat Gastroesophageal Reflux Disease (GERD)

Policy #: 506
Category: Surgery

Latest Review Date: November 2017
Policy Grade: C

Background:
Blue Advantage *medical policy does not conflict with Local Coverage Determinations (LCDs), Local Medical Review Policies (LMRPs) or National Coverage Determinations (NCDs) or with coverage provisions in Medicare manuals, instructions or operational policy letters. In order to be covered by Blue Advantage the service shall be reasonable and necessary under Title XVIII of the Social Security Act, Section 1862(a)(1)(A). The service is considered reasonable and necessary if it is determined that the service is:*

1. *Safe and effective;*
2. *Not experimental or investigational*;*
3. *Appropriate, including duration and frequency that is considered appropriate for the service, in terms of whether it is:*

    - *Furnished in accordance with accepted standards of medical practice for the diagnosis or treatment of the patient's condition or to improve the function of a malformed body member;*
    - *Furnished in a setting appropriate to the patient's medical needs and condition;*
    - *Ordered and furnished by qualified personnel;*
    - *One that meets, but does not exceed, the patient's medical need; and*
    - *At least as beneficial as an existing and available medically appropriate alternative.*

Routine costs of qualifying clinical trial services with dates of service on or after September 19, 2000 which meet the requirements of the Clinical Trials NCD are considered reasonable and necessary by Medicare. Providers should bill* ***Original Medicare* *for covered services that are related to* ***clinical trials*** *that meet Medicare requirements (Refer to Medicare National Coverage Determinations Manual, Chapter 1, Section 310 and Medicare Claims Processing Manual Chapter 32, Sections 69.0-69.11).*

Description of Procedure or Service:

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 10-20% 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's 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, 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.

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 (MRI) is needed for another condition.

Policy:

Effective for dates of service on or after February 26, 2018 refer to LCD L34434

Effective for dates of service on or after November 1, 2012 and prior to February 26, 2018:
Blue Advantage will treat an **implantable magnetic esophageal ring** to treat gastroesophageal reflux disease (GERD) as a **non-covered benefit** and as **investigational.**

Blue Advantage does not approve or deny procedures, services, testing, or equipment for our members. Our decisions concern coverage only. The decision of whether or not to have a certain test, treatment or procedure is one made between the physician and his/her patient. Blue Advantage administers benefits based on the members' contract and medical policies. Physicians should always exercise their best medical judgment in providing the care they feel is most appropriate for their patients. Needed care should not be delayed or refused because of a coverage determination.

Key Points:

The most recent literature update was performed through September 11, 2017.

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. 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 Comparative Trials

Retrospective comparative studies have been identified on magnetic sphincter augmentation (MSA) with the LINX® device compared with laparoscopic Nissen fundoplication (LNF) or laparoscopic Toupet fundoplication (LTF).

The largest study identified is a multi-institutional retrospective cohort study by Warren et al (2016) who reported on 415 patients treated with either MSA (n=201) or LNF (n=214). Eligible patients were retrospectively identified from 3 centers' prospectively-collected databases, and met criteria if they had GERD at least partially responsive to PPI treatment and positive pH testing. MSA-treated patients had lower DeMeester scores, and lower rates of biopsy-proven Barrett esophagus and hiatal hernia. Given the differences in baseline groups, the authors used propensity score matching to generate 114 matched pairs based on preoperative esophagitis, presence of Barret esophagus, hiatal hernia, and body mass index (BMI). Mean follow up differed for matched pair MSA and LNF groups (11 mo vs 16 mo, respectively, P<0.001). In quality of life analysis at follow-up, there was no significant difference in match-pair groups in GERD Health-Related Quality-of-Life (HRQL) scores (6 for MSA vs 5 for LNF, P=0.54). The proportion of patients using PPI at follow up was higher in the MSA group (24% vs 12%, P=0.02), but more patients in the MSA group had the ability for eructation (97% vs 66%, P<0.001).

Also in 2016, Asti et al reported on an observational cohort study comparing MSA (n=135) and laparoscopic Toupet fundoplication (LTF, n=103), using patients identified from a prospectively collected database. Eligible patients had GERD symptoms despite PPI for at least 6 months, and normal esophageal motility. In a generalized estimating equations (GEE) model for GERD-HRQL, there was no significant difference at 1 year in GERD-HRQL between MSA and LTF groups (OR for time-treatment interaction term: 1.04, 95% CI 0.89 to 1.27, P=0.578). Similarly,

there was no significant difference between the MSA and LTF groups at 1 year in PPI use (OR for time-treatment interaction term: 1.18, 95% CI 0.81 to 1.70, P=0.3888).

Reynolds et al (2015) reported one year follow-up of 50 MSA and 50 LNF patients matched for disease severity. 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 six months; and (3) normal esophageal motility. Some of the patients had been included in previous reports. At one year after surgery, the two 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 et al (2014) compared outcomes from 34 patients who had MSA with 32 patients who underwent LNF. Similar improvements were found for the two groups on the GERD-HRQL scale. The DeMeester score and pH normalized in both groups, but these were lower (p=.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.

In 2015, Riegler et al published one year results of an industry-sponsored multicenter registry (NCT01624506) that included a comparison with laparoscopic fundoplication. 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 two groups.

Section Summary: Nonrandomized Comparative Studies

Observational comparative studies, most often comparing MSA with LNF, generally show that GERD-HRQL does not differ significantly between fundoplication and MSA, and patients are able to reduce PPI use after MSA. However, these studies are limited by baseline differences in baseline characteristics of patients treated with MSA and fundoplication. Some studies adjust for some of the differences by matching for patient characteristics in their analyses, although the potential for residual confounding remains.

Single-Arm Studies
Data submitted to the U.S. Food and Drug Administration (FDA) for the LINX® Reflux Management System included two single-arm FDA-regulated investigational device exemption (IDE) trials with a total of 144 subjects and follow-up data between two and four years. The feasibility IDE study enrolled 44 subjects at four clinical sites (two U.S. and two Europe) and has published data out to four years. The pivotal IDE study included 100 subjects from 14 clinical sites (13 U.S. and one Europe) who had documented symptoms of gastroesophageal reflux disease for longer than six 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 four 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.

Results of the pivotal trial were published in 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 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 one year, and in 4% at three 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 four of these six patients with an SAE and in two additional patients for persistent reflux and chest pain.

Five year results from 33 of the 44 patients from the feasibility IDE trial were published in 2015. For the 33 with follow up, the mean total GERD-HRQL decreased from 25.7 at baseline to 2.9 at year 5 ($P<0.001$); 93.9% had more than 50% reduction in total score versus baseline. On esophageal pH testing, the mean percentage of time that pH was less than 4 decreased from 11.9% at baseline to 4.6% at 5 years ($P<0.001$). At 5 years, 87.8% had stopped PPIs.

Five year results for the 100 patients in the pivotal IDE trial were published in 2016. Eighty-five patients had follow up at 5 years. Of those 85, 83% achieved had a 50% reduction in GERD-HRQL (95% CI 73% to 91%) and 89.4% had a reduction in 50% or more in average daily dose of PPI (95% CI 81 to 95%). No new major safety concerns emerged. The device was removed in 7 patients.

In 2013, Bonavina et al published longer follow-up from some patients in the pilot and multicenter registry studies. This study included a consecutive series of 100 patients who received MSA for GERD at their institution and were followed for a median of three years (range, 378 days to six years). Thirty of the patients had data beyond five years. The median GERD-HRQL score improved from 24 off PPIs to two ($p<0.001$), and freedom from daily dependence on PPIs was achieved in 85% of patients. The time that esophageal pH was less than four decreased from 8.0% to 3.2% ($p<0.001$). Although three 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). Of these, 144 were implanted as part of premarket clinical trials (described above), 332 had been enrolled in a post market registry, and 572 were implanted outside of a postmarket registry. The three 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 one 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.

Additional single-arm observational studies have reported on outcomes after MSA in sample sizes ranging from 121 to 192, some of which have focused on specific subpopulations of individuals with GERD, such as those with large hiatal hernias (e.g. Rona et al, 2016).

Summary

For individuals who have GERD who receive magnetic esophageal ring, the evidence includes prospective and retrospective observational comparative studies, 2 single arm interventional trials, and a number of single arm observational studies. Relevant outcomes include symptoms, change in disease status, medication use, and treatment-related morbidity. In the 2 single arm uncontrolled manufacturer-sponsored studies that were submitted to the U.S. Food and Drug Administration (FDA) for device approval, subjects showed improvements in GERD-health related quality of life (HRQL) and reduced proton pump inhibitor (PPI) use. Similarly, observational comparative studies, most often comparing MSA with LNF, generally show that GERD-HRQL does not differ significantly between fundoplication and MA, 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 (e.g. the Gastroesophageal Reflux Disease- Health Related Quality of Life scores) may be biased. A randomized trial is in progress that will compare treatment with the magnetic esophageal ring 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. 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 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.

Key Words:

Gastroesophageal Reflux, GERD, LINX™, The LINX™ Reflux Management System (Torax Medical), magnet esophageal ring

Approved by Governing Bodies:

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 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 initially required five-year follow-up of 100 patients from the investigational device exemption (IDE) pivotal study to evaluate safety and efficacy of the device, which was completed in March 2016.

Benefit Application:

Coverage is subject to member's specific benefits. Group specific policy will supersede this policy when applicable.

Current Coding:

CPT Codes:

Effective 01/01/17, there are specific CPT codes for this procedure:

43284	Laparoscopy, surgical, esophageal sphincter augmentation procedure, placement of sphincter augmentation device (i.e., magnetic band), including cruroplasty when performed **(Effective 01/01/17)**
43285	Removal of esophageal sphincter augmentation device **(Effective 01/01/17)**

Previous Coding

CPT Codes:

43289	unlisted laparoscopy procedure, esophagus **(Replaced effective 07/01/2015)**
0392T	Laparoscopy, surgical, esophageal sphincter augmentation procedure, placement of sphincter augmentation device (i.e., magnetic band) **(Deleted 12/31/16)**
0393T	Removal of esophageal sphincter augmentation device **(Deleted 12/31/16)**

HCPCS:

C9737	Lap esoph augmentation **(Deleted 07/01/2015))**

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