Corporate Medical Policy

Magnetic Esophageal Sphincter Augmentation to Treat Gastroesophageal Reflux Disease (GERD)

File Name: magnetic_esophageal_sphincter_augmentation_to_treat_gastroesophageal_reflux_disease (GERD)
Origination: 10/2012
Last Review: 11/2022

Description of Procedure or Service

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 individuals who have GERD symptoms despite maximum medical therapy.

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 individuals have mild, intermittent symptoms that do not require treatment or only require episodic use of medications. Other individuals have chronic, severe GERD that can lead to complications such as Barrett's esophagus and esophageal cancer. For individuals with severe disease, chronic treatment with acid suppressive therapies is one option. For some individuals, medications are not adequate to control symptoms, and other individuals prefer to avoid the use of indefinite, possibly lifelong medications. Surgical treatments are available for these individuals, 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 individuals 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 individuals 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. 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. In 2018,the manufacturer initiated a device recall due to a possible separation of the bead

component with the adjacent wire link causing a potential discontinuous or open LINX device. This recall was terminated on November 4, 2020.

In March 2018, the FDA approved an update of the LINX® Reflux Management System precautions statement, stating that the use of the system "in patients with a hiatal hernia larger than 3 cm should include hiatal hernia repair to reduce the hernia to less than 3 cm and that the LINX Reflux Management System has not been evaluated in patients with an unrepaired hiatal hernia greater than 3 cm, add a hiatal hernia clinical data summary in the instructions for use, update the instructions for use section to highlight the recommendation to repair a hiatal hernia, if present, at the time of the LINX Reflux Management System implantation, and update the patient information booklet to align with the instructions for use and include 5 year clinical study results."

Related Policies
Gastroesophageal Reflux Disease, Transesophageal Endoscopic Therapies

******Note: This Medical Policy is complex and technical. For questions concerning the technical language and/or specific clinical indications for its use, please consult your physician.***

Policy

Magnetic esophageal sphincter augmentation to treat gastroesophageal reflux disease (GERD) may be considered medically necessary when the medical criteria and guidelines outlined below are met.

Benefits Application

This medical policy relates only to the services or supplies described herein. Please refer to the Member's Benefit Booklet for availability of benefits. Member's benefits may vary according to benefit design; therefore member benefit language should be reviewed before applying the terms of this medical policy.

When it is covered

Laparoscopic magnetic sphincter augmentation (LINX™ Reflux Management System) may be considered medically necessary in individuals 18 years and older when:

- the individual has chronic, bothersome symptomatic gastroesophageal reflux (GERD) established by endoscopy, fluoroscopy or ambulatory pH testing that is inadequately controlled with individually appropriate daily proton pump inhibitor (PPI) use (unless intolerant to or contraindicated) for at least 6 months or a need to stop PPI therapy; AND
- for those individuals with a hiatal hernia greater than 3 centimeters (cm), the hiatal hernia will be repaired prior to or at the same time as the LINX procedure; AND
- the LINX is being used as an alternative to surgical fundoplication for symptomatic GERD; AND
- the procedure is being performed by a physician who has completed procedure-specific training in the use of the LINX system with privileges to perform the procedure, AND
- the individual is enrolled in the NC BEST (North Carolina Blue Cross Blue Shield Esophageal Therapeutics) registry that prospectively and uniformly collects prespecified clinical outcomes (see Policy Guidelines).

When it is not covered

Use of laparoscopic magnetic sphincter augmentation (LINX™ Reflux Management System) is considered investigational in individuals with any of the following:

- those individuals not enrolled in the NC BEST registry
- a body-mass-index (BMI) over 35 Kg/m2
- esophageal motility disorder*
- hiatal hernia greater than 3 cm
- active esophageal or gastric cancer
- presence of electrical implant
- esophageal or gastric varices or strictures
- scleroderma
- preoperative dysphagia more than once a week for past 3 months

*Major esophageal motility disorders include achalasia, distal esophageal spasm, hypercontractile esophagus and absent contractility. This does not include minor disorders of peristalsis, e.g., ineffective esophageal motility [IEM]).

Policy Guidelines

The North Carolina Blue Cross Blue Shield Esophageal Therapeutics (NC BEST) Registry will evaluate the efficacy and safety of magnetic sphincter augmentation (LINX®) for the management of gastroesophageal reflux disease (GERD). The study, conducted at Duke University, has a primary endpoint of percentage of individuals with at least 50% reduction in GERD symptoms as measured by GERD-HRQL (health-related quality of life) score as compared to baseline without the use of proton pump inhibitors (PPIs) and a reduction of at least 50% in the average daily dose of PPIs compared with baseline at 12 months.

For individuals who have GERD who receive magnetic sphincter augmentation (MSA), the evidence includes one randomized controlled trial comparing MSA to proton pump inhibitor therapy, a single nonrandomized registry study comparing MSA to laparoscopic fundoplication, single-arm cohort studies, and systematic reviews of observational studies comparing MSA to laparoscopic Nissen fundoplication. Relevant outcomes are symptoms, change in disease status, medication use, and treatment-related morbidity. A randomized controlled trial comparing MSA to omeprazole 20 mg twice daily found significantly more individuals who received MSA reported improvements in symptoms and quality of life at six months. A major limitation of the trial was that the individuals had not received optimal medical treatment prior to enrollment. A prospective, observational registry study comparing MSA to laparoscopic fundoplication found similar improvements in quality of life, satisfaction, and medication use. Limitations of the study included lack of randomization and blinding, heterogeneity in fundoplication techniques, use of an outdated MSA protocol, and selection bias as patients with less severe symptoms received MSA. In the two single-arm, uncontrolled pivotal trials submitted to the U.S. Food and Drug Administration with materials for device approval, subjects showed improvements in GERD-health-related quality of life scores and reduced proton pump inhibitor use. Similarly, observational comparative studies included in systematic reviews, most often comparing MSA with laparoscopic Nissen fundoplication, generally have shown that GERD-health-related quality of life scores do not differ significantly between fundoplication and MSA, and individuals can reduce proton pump inhibitor use after MSA. However, the comparative studies are retrospective and nonrandomized, and may be affected by selection bias. Randomized comparisons of MSA with laparoscopic Nissen fundoplication are needed to evaluate the relative risk-benefit of these two procedures.

Billing/Coding/Physician Documentation Information

This policy may apply to the following codes. Inclusion of a code in this section does not guarantee that it will be reimbursed. For further information on reimbursement guidelines, please see Administrative

Policies on the Blue Cross Blue Shield of North Carolina web site at www.bcbsnc.com. They are listed in the Category Search on the Medical Policy search page.

Applicable code: *43284, 43285*

BCBSNC may request medical records for determination of medical necessity. When medical records are requested, letters of support and/or explanation are often useful, but are not sufficient documentation unless all specific information needed to make a medical necessity determination is included.

Scientific Background and Reference Sources

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.137, 8/9/12

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.137, 8/8/13

Specialty Matched Consultant Advisory Panel 11/2013

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.137, 8/14/14

Specialty Matched Consultant Advisory Panel 11/2014

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.137, 8/13/15

Specialty Matched Consultant Advisory Panel 11/2015

Specialty Matched Consultant Advisory Panel 11/2016

For Policy titled Magnetic Esophageal Sphincter Augmentation to Treat Gastroesophageal Reflux Disease (GERD)

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.137, 11/10/2016

Specialty Matched Consultant Advisory Panel 11/2017

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.137, 11/9/2017

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.137, 11/8/2018

Specialty Matched Consultant Advisory Panel 11/2018

Specialty Matched Consultant Advisory Panel 11/2019

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.137, 11/14/2019

Specialty Matched Consultant Advisory Panel 11/2020

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.137, 11/12/2020

Specialty Matched Consultant Advisory Panel 11/2021

Medical Director review 7/2022

Specialty Matched Consultant Advisory Panel 11/2022

Policy Implementation/Update Information

10/16/12 New policy issued. An implantable magnetic esophageal ring to treat gastroesophageal reflux disease (GERD) is considered investigational. Medical Director review 8/2012. (sk)

12/31/13 Reference added. Specialty Matched Consultant Advisory Panel review 11/20/2013. Medical Director review. HCPCS code C9737 added to Billing/Coding section effective 01/01/2014. CPT 43289 removed from Billing/Coding section. No change to Policy statement. (sk)

10/14/14 Reference added. Policy Guidelines updated. No change to Policy statement. (sk)

12/9/14 Specialty Matched Consultant Advisory Panel review 11/24/2014. No change to Policy statement. (sk)

7/1/15 HCPCS code C9737 deleted effective 6/30/2015. CPT code 0392T and 0393T added effective 7/1/2015. (sk)

10/1/15 Reference added. (sk)

12/30/15 Specialty Matched Consultant Advisory Panel review 11/18/2015. (sk)

12/30/16 Specialty Matched Consultant Advisory Panel review 11/22/2016. Codes 43284 and 43285 added to Billing/Coding section. Codes 0392T and 0393T deleted from Billing/Coding section. (sk)

For Policy titled Magnetic Esophageal Sphincter Augmentation to Treat Gastroesophageal Reflux Disease (GERD)

1/27/17 Reference added. Policy Guidelines updated. Title changed from Magnetic Esophageal Ring to Treat Gastroesophageal Disease (GERD) to Magnetic Esophageal Sphincter Augmentation to Treat Gastroesophageal Reflux Disease (GERD). No change to policy statement. Codes 0392T and 0393T added to Billing/Coding section. (sk)

12/15/17 Specialty Matched Consultant Advisory Panel review 11/29/2017. (sk)

1/26/18 Reference added. (sk)

12/14/18 Reference added. Specialty Matched Consultant Advisory Panel review 11/28/2018. (sk)

6/23/20 Specialty Matched Consultant Advisory Panel review 11/20/2019. Reference added. (sk)

12/8/20 Specialty Matched Consultant Advisory Panel review 11/18/2020. (sk)

11/30/21 Reference added. Specialty Matched Consultant Advisory Panel review 11/17/2021. (sk)

7/26/22 Medical Director review. When Covered section updated to state that laparoscopic magnetic esophageal sphincter augmentation may be considered medically necessary when criteria are met. When Not Covered section updated with non-covered criteria. Policy Guidelines updated. (sk)

5/2/23 Policy review. Regulatory Status updated. Policy Guidelines updated. Specialty Matched Consultant Advisory Panel review 11/16/2022. (sk)