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 CAP Review: 11/2020
Next CAP Review: 11/2021
Last Review: 11/2020

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 patients 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 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.

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 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.

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) is considered investigational. BCBSNC does not provide coverage for investigational services or procedures.

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

Not applicable.

When it is not covered

Magnetic esophageal sphincter augmentation to treat gastroesophageal reflux disease (GERD) is considered investigational.

Policy Guidelines

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, comparative observational studies of MSA vs. laparoscopic Nissen fundoplication, single-arm cohort studies, and systematic reviews of observational studies. 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 patients who received MSA reported improvements in symptoms and quality of life at six months. A major limitation of the trial was that the patients had not received optimal medical treatment prior to enrollment. In the two 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 scores and reduced proton pump inhibitor use. Similarly, observational comparative studies, 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 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-health-related quality of life scores) may be biased. Randomized comparisons of MSA with laparoscopic Nissen fundoplication are needed to evaluate the relative risk-benefit of these two procedures. The evidence is insufficient to determine the effects of the technology on health outcomes.

Billing/Coding/Physician Documentation Information

An Independent Licensee of the Blue Cross and Blue Shield Association

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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

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)

Medical policy is not an authorization, certification, explanation of benefits or a contract. Benefits and eligibility are determined before medical guidelines and payment guidelines are applied. Benefits are determined by the group contract and subscriber certificate that is in effect at the time services are rendered. This document is solely provided for informational purposes only and is based on research of current medical literature and review of common medical practices in the treatment and diagnosis of disease. Medical practices and knowledge are constantly changing and BCBSNC reserves the right to review and revise its medical policies periodically.