# Magnetic Esophageal Sphincter Augmentation to Treat Gastroesophageal Reflux Disease

**BCBSA Ref. Policy:** 7.01.137  
**Effective Date:** Jan. 1, 2018  
**Last Revised:** Dec. 6, 2017  
**Replaces:** N/A  

<table>
<thead>
<tr>
<th>RELATED MEDICAL POLICIES:</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>2.01.38</td>
<td>Transesophageal Endoscopic Therapies for Gastroesophageal Reflux Disease</td>
</tr>
<tr>
<td>2.01.91</td>
<td>Peroral Endoscopic Myotomy (POEM) for Treatment of Esophageal Achalasia</td>
</tr>
</tbody>
</table>

## Introduction

GERD — gastroesophageal reflux disease — is a long-term medical condition. It’s a digestive problem that affects the ring of muscles between the esophagus (the tube that carries swallowed food to the stomach) and the stomach. When food is swallowed, the muscles at the end of the esophagus open so food can pass into the stomach. The muscles then close to prevent acid from backing up into the esophagus. In GERD, however, the ring of muscles is too weak. GERD is usually treated with changes to lifestyle and diet. A number of other treatments have been studied. One technique calls for placing a ring of magnetic beads around the base of the esophagus, just above the stomach. The ring opens to allow swallowed food into the stomach and then immediately tightens. This technique is investigational (unproven). More and longer studies are needed to find out how well such devices work.

**Note:** The Introduction section is for your general knowledge and is not to be taken as policy coverage criteria. The rest of the policy uses specific words and concepts familiar to medical professionals. It is intended for providers. A provider can be a person, such as a doctor, nurse, psychologist, or dentist. A provider also can be a place where medical care is given, like a hospital, clinic, or lab. This policy informs them about when a service may be covered.
Policy Coverage Criteria

<table>
<thead>
<tr>
<th>Service</th>
<th>Investigational</th>
</tr>
</thead>
<tbody>
<tr>
<td>Magnetic esophageal sphincter augmentation</td>
<td>Magnetic esophageal sphincter augmentation to treat gastroesophageal reflux disease is considered investigational.</td>
</tr>
<tr>
<td></td>
<td>Note: Commercially available esophageal sphincter augmentation device: The LINX™ Reflux Management System (Torax Medical)</td>
</tr>
</tbody>
</table>

Coding

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>CPT</td>
<td></td>
</tr>
<tr>
<td>43284</td>
<td>Laparoscopy, surgical, esophageal sphincter augmentation procedure, placement of sphincter augmentation device (ie, magnetic band), including cruroplasty when performed</td>
</tr>
<tr>
<td>43285</td>
<td>Removal of esophageal sphincter augmentation device</td>
</tr>
</tbody>
</table>

Note: CPT codes, descriptions and materials are copyrighted by the American Medical Association (AMA). HCPCS codes, descriptions and materials are copyrighted by Centers for Medicare Services (CMS).

Related Information

N/A

Evidence Review
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 maximal medical therapy.

Background

Gastroesophageal Reflux Disease
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 varies widely. 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.

Treatment
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 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 (eg, proton pump inhibitors) but who do not want to risk having 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.

**Summary of Evidence**

For individuals who have GERD who receive MSA, the evidence includes prospective and retrospective observational comparative studies, 2 single-arm interventional trials, and a number of single-arm observational studies. Relevant outcomes are symptoms, change in disease status, medication use, and treatment-related morbidity. In the 2 single-arm, uncontrolled manufacturer-sponsored studies submitted to the U.S. Food and Drug Administration for device approval, subjects showed improvements in GERD-HRQL scores and reduced proton pump inhibitor use. Similarly, observational comparative studies, most often comparing MSA with laparoscopic Nissen fundoplication, generally have shown that GERD-HRQL 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-HRQL scores) may be biased. A randomized trial is in progress (NCT02505945); it will compare treatment with the MSA and treatment with double-dose proton pump inhibitors. Randomized comparisons of MSA with laparoscopic 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.

**Ongoing and Unpublished Clinical Trials**

Some trials that might influence this policy are listed in Table 1.

<table>
<thead>
<tr>
<th>NCT No.</th>
<th>Trial Name</th>
<th>Planned Enrollment</th>
<th>Completion Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ongoing</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>NCT02505945a</td>
<td>The CALIBER Study Randomized Controlled Trial of LINX Versus Double-Dose Proton Pump Inhibitor Therapy for</td>
<td>150</td>
<td>Jun 2018</td>
</tr>
<tr>
<td>NCT No.</td>
<td>Trial Name</td>
<td>Planned Enrollment</td>
<td>Completion Date</td>
</tr>
<tr>
<td>-------------------</td>
<td>-----------------------------------------------------------------------------</td>
<td>--------------------</td>
<td>-----------------</td>
</tr>
<tr>
<td>NCT01940185</td>
<td>A Post-Approval Study of the Lynx® Reflux Management System</td>
<td>200</td>
<td>Sep 2019</td>
</tr>
</tbody>
</table>

NCT: national clinical trial

*a Denotes industry-sponsored or cosponsored trial.

Practice Guidelines and Position Statements

**Society of American Gastrointestinal and Endoscopic Surgeons**

In 2013, the Society of American Gastrointestinal and Endoscopic Surgeons published guidelines on the safety and effectiveness of the LINX Reflux Management System. The Society indicated that safety analyses of the LINX system suggested the procedure is associated with few serious adverse events and no reported mortality, and that currently available data demonstrated a reasonable assurance as to the efficacy of the system. The guidelines concluded that direct comparative studies between the LINX procedure and Nissen fundoplication would be needed. But based on the available evidence, the LINX device should be an option available to patients and providers for the management of medically refractory gastroesophageal reflux disease.

**American Society for Gastrointestinal Endoscopy**

A 2017 report from the American Society for Gastrointestinal Endoscopy concluded that long-term data about the safety and efficacy of the LINX device were needed. The document indicates that the LINX band is currently being deployed laparoscopically; however, a natural orifice transluminal endoscopic surgery approach could be explored.

**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.
Regulatory Status

In 2012, the LINX™ Reflux Management System (Torax Medical, Shoreview, MN) was approved by the U.S. Food and Drug Administration 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 Food and Drug Administration 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. Food and Drug Administration product code: LEI.

References


-------

**History**

<table>
<thead>
<tr>
<th>Date</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>10/15/12</td>
<td>New Policy. Policy created with literature review through June 2012; considered investigational.</td>
</tr>
<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>
</tr>
<tr>
<td>11/20/13</td>
<td>Update Related Policies. Add 2.01.91.</td>
</tr>
<tr>
<td>01/30/14</td>
<td>Update Related Policies. Change title to 2.01.38.</td>
</tr>
<tr>
<td>Date</td>
<td>Comments</td>
</tr>
<tr>
<td>------------</td>
<td>---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>01/28/16</td>
<td>Minor update. Added CPT codes 0392T and 0393T, effective 7/1/15, to the coding table.</td>
</tr>
<tr>
<td>11/08/16</td>
<td>Annual review. Policy title changed to &quot;Magnetic Esophageal Sphincter Augmentation to Treat Gastroesophageal Reflux Disease&quot;, 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.</td>
</tr>
<tr>
<td>01/01/17</td>
<td>Minor Coding update; added note that CPT codes 43284 and 43285 are new codes effective 1/1/17.</td>
</tr>
<tr>
<td>06/09/17</td>
<td>Coding update; removed CPT codes 0392T and 0393T as they were terminated as of 1/1/17.</td>
</tr>
<tr>
<td>01/01/18</td>
<td>Annual Review, approved December 6, 2017. Policy updated with literature review through September 2017; no references added; references 7 and 19 updated. Policy statement unchanged. Removed CPT code 43289.</td>
</tr>
</tbody>
</table>

**Disclaimer:** This medical policy is a guide in evaluating the medical necessity of a particular service or treatment. The Company adopts policies after careful review of published peer-reviewed scientific literature, national guidelines and local standards of practice. Since medical technology is constantly changing, the Company reserves the right to review and update policies as appropriate. Member contracts differ in their benefits. Always consult the member benefit booklet or contact a member service representative to determine coverage for a specific medical service or supply. CPT codes, descriptions and materials are copyrighted by the American Medical Association (AMA). ©2018 Premera All Rights Reserved.

**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.
Discrimination is Against the Law

Premera Blue Cross complies with applicable Federal civil rights laws and does not discriminate on the basis of race, color, national origin, age, disability, or sex. Premera does not exclude people or treat them differently because of race, color, national origin, age, disability or sex.

Premera:
- Provides free aids and services to people with disabilities to communicate effectively with us, such as:
  - Qualified sign language interpreters
  - Written information in other formats (large print, audio, accessible electronic formats, other formats)
- Provides free language services to people whose primary language is not English, such as:
  - Qualified interpreters
  - Information written in other languages

If you need these services, contact the Civil Rights Coordinator.

If you believe that Premera has failed to provide these services or discriminated in another way on the basis of race, color, national origin, age, disability, or sex, you can file a grievance with:

Civil Rights Coordinator - Complaints and Appeals
PO Box 91102, Seattle, WA 98111
Toll free 855-332-4535, Fax 425-918-5592, TTY 800-842-5357
Email AppealsDepartmentInquiries@Premera.com

You can file a grievance in person or by mail, fax, or email. If you need help filing a grievance, the Civil Rights Coordinator is available to help you.

You can also file a civil rights complaint with the U.S. Department of Health and Human Services, Office for Civil Rights, electronically through the Office for Civil Rights Complaint Portal, available at:
https://ocrportal.hhs.gov/ocr/portal/lobby.jsf, or by mail or phone at:
U.S. Department of Health and Human Services
200 Independence Avenue SW, Room S09F, HHH Building
Washington, D.C. 20201, 1-800-368-1019, 800-537-7697 (TDD)
Complaint forms are available at:

Getting Help in Other Languages

This Notice has Important Information. This notice may have important information about your application or coverage through Premera Blue Cross. There may be key dates in this notice. You may need to take action by certain deadlines to keep your health coverage or help with costs. You have the right to get this information and help in your language at no cost.

Call 800-722-1471 (TTY: 800-842-5357).


Ilokano (Ilocano): Daytoy a Pakdaak ket naglao iti Napateg nga Impormasion. Daytoy a pakdaak mabalin nga adda ket naglao iti napateg nga impormasion maiyaggepp iti aplicasyonono wenno coverage babaen iti Premera Blue Cross. Daytoy ket mabalin dagiti importante a pelta iti daytoy a pakdaak. Mabalin nga adda rumbeng nga aramidenyo nga addang sakyab dagiti partikular a naituding nga adda aldaw tapao mapattalindayyo iti taygo ti salan-atyo wenno tulong kadagit gastos. Adda karbenganyo a mangala iti daytoy nga impormasion ken tulong ti bukodyo a pagasasao nga awan ti bayadayno. Tumawag ti numero nga 800-722-1471 (TTY: 800-842-5357).

Premera Blue Cross

Atonu ua i i le lenei fa’asilasi la ni fa’amatala e sili ona taua e tatau ona e malamalama i ai. O lenei fa’asilasi la o se fesoasoani e fa’amatala ona taua e tatau ona e malamalama i ai. Fa’amoleme, ia e ilole fa’alele e asa fa’apito o iao la i lenei fa’asilasi la taula. Masolo o le a iai ni feau e tatau ona e faia aoe le i o i aia le a ao o iao la a ao. Ato la i i le fa’amatala o le Malo olo o i i ai. Olo la o i i ai le aia tatau e mafua atu la i lenei fa’asilasi la ni lenei fa’amatala e legagana e te malamalama i ai aunoa ma se topiga tupe. Vili atu le i le telefoni 800-722-1471 (TTY: 800-842-5357).

Fa’asamoa (Samoan):


English (English):

Premera Blue Cross

You may need to take certain actions before certain dates as stated in this notice. This notice may contain important information about your coverage and/or assistance to pay the costs.

800-722-1471 (TTY: 800-842-5357) or visit our website.

Premera Blue Cross

To og

This notice contains important information that may affect your coverage or the amounts you pay for care. It may contain information about how you can keep your coverage or get help with costs.

800-722-1471 (TTY: 800-842-5357) or visit our website.

Portuguese (Portuguese):

Este aviso contém informações importantes. Este aviso poderá conter informações importantes a respeito de sua aplicação ou cobertura por meio do Premera Blue Cross. Poderão existir datas importantes neste aviso. Talvez seja necessário que você tome providências dentro de determinados prazos para manter sua cobertura de saúde e ajuda de custos. Você tem o direito de obter esta informação e ajuda em seu idioma e sem custos. Ligue para 800-722-1471 (TTY: 800-842-5357).

Español (Spanish):

Este aviso contiene información importante. Es posible que este aviso contenga información importante acerca de su solicitud de cobertura a través de Premera Blue Cross. Es posible que haya fechas claras en este aviso. Es posible que deba tomar alguna medida antes de determinadas fechas para mantener su cobertura médica o ayuda con los costos. Usted tiene derecho a recibir esta información y ayuda en su idioma sin costo alguno. Líame al 800-722-1471 (TTY: 800-842-5357).

Română (Romanian):