MEDICAL POLICY – 7.01.137
Magnetic Esophageal Sphincter Augmentation to Treat Gastroesophageal Reflux Disease

BCBSA Ref. Policy: 7.01.137
Effective Date: Feb. 1, 2021
Last Revised: Jan. 6, 2021
Replaces: N/A

RELATED MEDICAL POLICIES:
2.01.38 Transesophageal Endoscopic Therapies for Gastroesophageal Reflux Disease
2.01.91 Peroral Endoscopic Myotomy for Treatment of Esophageal Achalasia

Select a hyperlink below to be directed to that section.

POLICY CRITERIA | CODING | RELATED INFORMATION
EVIDENCE REVIEW | REFERENCES | HISTORY

∞ Clicking this icon returns you to the hyperlinks menu above.

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><strong>Magnetic esophageal sphincter augmentation</strong></td>
<td><strong>Magnetic esophageal sphincter augmentation to treat gastroesophageal reflux disease is considered investigational.</strong></td>
</tr>
</tbody>
</table>

**Note:** Commercially available esophageal sphincter augmentation device: The LINX™ Reflux Management System (Torax Medical)

## 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.

Treatment

For patients with severe disease, chronic treatment with acid blockers is an option. For some patients, medications are inadequate 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 magnetic sphincter augmentation (MSA), the evidence includes one randomized controlled trial comparing MSA to proton pump inhibitor therapy, single-arm cohort studies, and systematic reviews of observational studies comparing MSA to laparoscopic Nissen fundoplication. The 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 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 (HRQL) scores and reduced proton pump inhibitor use. Similarly, observational comparative studies, most often comparing MSA with laparoscopic Nissen fundoplication (LNF), 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. 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.

**Ongoing and Unpublished Clinical Trials**

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

**Table 1. Summary of Key Trials**

<table>
<thead>
<tr>
<th>NCT No.</th>
<th>Trial Name</th>
<th>Planned Enrollment</th>
<th>Completion Date</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Ongoing</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>NCT02429830*</td>
<td>RELIEF Study: A Prospective, Multicenter Study of REflux Management With the LINX® System for</td>
<td>30</td>
<td>Oct 2019</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>NCT02923362</td>
<td>Gastroesophageal REFlux Disease After Laparoscopic Sleeve Gastrectomy</td>
<td></td>
<td></td>
</tr>
<tr>
<td>NCT01940185a</td>
<td>Registry of Outcomes From AntiReflux Surgery (ROARS)</td>
<td>2500</td>
<td>May 2025</td>
</tr>
<tr>
<td>NCT04253392a</td>
<td>A Post-Approval Study of the Lynx® Reflux Management System</td>
<td>200</td>
<td>Oct 2025</td>
</tr>
<tr>
<td></td>
<td>RETHINK REFLUX Registry (RETHINK REFLUX)</td>
<td>500</td>
<td>July 2032</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

The Society of American Gastrointestinal and Endoscopic Surgeons (SAGES, 2013; updated in 2017) published guidelines on the safety and effectiveness of the LINX Reflux Management System. The SAGES 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, although 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

In 2013, a report from the American Society for Gastrointestinal Endoscopy concluded that long-term data on the safety and efficacy of the LINX device were needed. The document indicated 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.
Regulatory Status

In 2012, the LINX™ Reflux Management System (Torax Medical) was approved by the U.S. Food and Drug Administration (FDA) through the premarket approval process (P100049) 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. The 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.¹

FDA 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>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 “Magnetic Esophageal Sphincter Augmentation to Treat Gastroesophageal Reflux Disease”, 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>Date</td>
<td>Comments</td>
</tr>
<tr>
<td>----------</td>
<td>----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------</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>
<tr>
<td>02/01/19</td>
<td>Annual Review, approved January 4, 2019. Policy updated with literature review through September 2018; no references added. Policy statement unchanged.</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). ©2021 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)

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).

Arabic (Arabic):
يحوي هذا الإشعار معلومات هامة. قد يحوي هذا الإشعار معلومات مهمة يخصك تلميذ. إن تكون هذه الإشارات، وهي خطيرة، فعلياً خصصاً لكل الحصص على تلك التعليمات، وإعدادات المعلومات والمتطلبات، تشمل:
800-722-1471 (TTY: 800-842-5357).

Chinese (Chinese):
本通知有重要的訊息。本通知可能有關於您透過 Premera Blue Cross 提交的申請或履歷的重要訊息。本通知可能有重要日期。您可能需要在截止日期之前採取行動。以保留您的健康保險或費用補貼，您有權利免費以您的母語得到本訊息和幫助。請撥電話 800-722-1471 (TTY: 800-842-5357).

Deutsche (German):

Italiano (Italian):

Français (French):

Kreyòl ayisyen (Creole):
Avi sila a gen Enfòmasyon Enpòtan lidann. Avi sila a kapab genyen enfòmasyon enpòtan konsènan aplikasyon w lan oswa konsènan kouvèti asirians lan atravè Premera Blue Cross. Kapab genyen dat ki enpòtan nan avi sila a. Ou ka gen pou pran kèk aksyon avan sèten dat limit pou ka kente kouvèti asirians sante w la oswa pou yo ka ede w akèk depans yo. Se dwa w pou resewa enfòmasyon sa a ak asistans nan lang ou pale a, san ou pa gen pou pèye pou sa. Rate nan 800-722-1471 (TTY: 800-842-5357).

Hmoob (Hmong):

Iloko (Ilocano):
Daytoy a Pakdaar ket nagliaon iti Napateg nga Impormasion. Daytoy a pakdaar mabalabin nga adda ket nagliaon iti napateg nga impormasion maipanggep iti aplikasyonنوو coverage babaen iti Premera Blue Cross. Daytoy ket mabalabin dagiti importante a pelsa iti daytoy a pakdaar. Mabalabin nga adda rumbeng nga aramidenyo nga addang sakyab dagiti partikular a naituding nga aldaw tapno mapagtalinaedyo ti coverage ti salun-atay wulo tulong kadagit gastos. Adda karbenganyo a mangala iti daytoy nga impormasion ken tulong iti bukodyo a pagasasao nga awan ti bayadanyo. Tumawag ti numero nga 800-722-1471 (TTY: 800-842-5357).

Lakkoofsa (Somali):
Oromoo (Cushite):

Tsab ntawv tshaj xo no muaj cov ntsiab lus tseem ceeb txog koj daim ntawv no. Tej zaum muaj cov hnub tseem ceeb uas sau rau hauv daim ntawv no. Tej zaum koj kuyu yuua taq qee yam uas peb koj ua tsip pub dhuav cov caij nyoy uas teev tseg rau hauv daim ntawv no mas kaj thaj yuva taq thais kev pab cuam kho kho los yoy kev pab teh tej nqi kho mob ntawv. Kaj muaj cai kom laww muab cov ntsiab lus no uas tau muab sau ua koj hom lus pub daww rau koj. Hu rau 800-722-1471 (TTY: 800-842-5357).

 appellations and addresses of certain Premera Blue Cross employees. Premera Blue Cross is not required to provide these services or discriminate in another way on the basis of race, color, national origin, age, disability, or sex.
Este aviso podrá contener información importante. Este aviso puede contener información importante privándonos de sabiduría de hechos y asistencia gratuita de costos. Pertenece a los datos de la solicitud de cobertura Premera Blue Cross. La portabilidad puede acontecer no para que el beneficio total para usted acepte la portabilidad de la seguridad de salud o asistencia gratuita a costos. 

Esto se debe a que tiene derecho a recibir esta información en su idioma sin costos alguno. Llamé al 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 en su idioma sin costos alguno. Llame al 800-722-1471 (TTY: 800-842-5357).


ไทย (Thai): ประกาศนี้มีข้อความสำคัญ ประกาศนี้มีข้อความสำคัญที่เกี่ยวกับการเปลี่ยนแปลงของสิทธิ์ของคุณในการซื้อหุ้นของ Premera Blue Cross และการปฏิบัติงานในกรณีที่คุณจะต้อง ด้วยการปฏิบัติการในทางกฎหมายที่เกี่ยวข้องเพื่อให้คุณทราบถึงข้อความสำคัญในการซื้อหุ้นของ Premera Blue Cross.

Український (Ukrainian): Це повідомлення містить важливу інформацію. Це повідомлення може містити важливу інформацію про Ваше звернення щодо страховчого покриття через Premera Blue Cross. Зверніть увагу на ключові дати, які можуть бути вказані у цьому повідомленні. Існує імовірність того, що Вам треба буде здійснити певні кроки у конкретні кінцеві строки для того, щоб зберегти Ваше медичне страхування або отримати фінансову допомогу. У Вас є право на отримання цієї інформації та допомоги безкоштовно на Вашій рідній мові. Дозвоніться за номером телефону 800-722-1471 (TTY: 800-842-5357).