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

BCBSA Ref. Policy: 7.01.137
Effective Date: Feb. 1, 2020
Last Revised: Jan. 9, 2020
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

Service | Investigational
Magnetic esophageal sphincter augmentation | Magnetic esophageal sphincter augmentation to treat gastroesophageal reflux disease is considered investigational.

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>
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</table>

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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, comparative observational studies of MSA vs laparoscopic Nissen fundoplication, single-arm cohort studies, and systematic reviews of observational studies. 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 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 (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, and the subjective outcome measures used in these studies (eg, the GERD-HRQL 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.

**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>
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<tr>
<td>NCT02429830a</td>
<td>RELIEF Study: A Prospective, Multicenter Study of REflux Management With the LINX® System for Gastroesophageal REFlux Disease After Laparoscopic Sleeve Gastrectomy</td>
<td>30</td>
<td>Oct 2019</td>
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<tr>
<td>NCT02923362</td>
<td>Registry of Outcomes From AntiReflux Surgery (ROARS)</td>
<td>2500</td>
<td>May 2025</td>
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<tr>
<td>NCT01940185a</td>
<td>A Post-Approval Study of the Lynx® Reflux Management System</td>
<td>200</td>
<td>Oct 2025</td>
</tr>
</tbody>
</table>

NCT: national clinical trial

* 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 (2013) published guidelines on the safety and effectiveness of the LINX Reflux Management System.¹¹ 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, 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**

A report from the American Society for Gastrointestinal Endoscopy (2013) concluded that long-term data on the safety and efficacy of the LINX device were needed.¹² 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 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 maximal 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


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### History

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<thead>
<tr>
<th>Date</th>
<th>Comments</th>
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<tr>
<td>10/15/12</td>
<td>New Policy. Policy created with literature review through June 2012; considered investigational.</td>
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<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>
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<td>11/20/13</td>
<td>Update Related Policies. Add 2.01.91.</td>
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<tr>
<td>01/30/14</td>
<td>Update Related Policies. Change title to 2.01.38.</td>
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<tr>
<td>01/28/16</td>
<td>Minor update. Added CPT codes 0392T and 0393T, effective 7/1/15, to the coding table.</td>
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<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>
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<td>Minor Coding update; added note that CPT codes 43284 and 43285 are new codes effective 1/1/17.</td>
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<td>Coding update; removed CPT codes 0392T and 0393T as they were terminated as of 1/1/17.</td>
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<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>
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**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

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Premera:
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  • 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 also 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 509F, 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).

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لا تتم التمييز بين الموظفين إذا كانوا من مجموعات مختلفة. لا تكون هناك ترخيص متماثل في هذه الجهة. يتم تقديم هذه المعلومات باللغة العربية في الخطة التغطية. قد تحتاج إلى إدراج إعدادات للغة تطبيقاتك على حسابك الشخصي للحصول على مستندات الحساب أو المعلومات. يمكن الحصول على هذه المعلومات والمساعدة باللغة العربية عبر الاتصال
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Questo avviso contiene informazioni importanti. Questo avviso può contenere informazioni importanti sulla tua domanda o copertura attraverso Premera Blue Cross. Potrebbero esserci date chiave in questo avviso. Potrebbe essere necessario un tuo intervento entro una scadenza determinata per consentirti di mantenere la tua copertura o sovvenzione. Hai il diritto di ottenere queste informazioni e assistenza nella tua lingua gratuitamente.
Chiama 800-722-1471 (TTY: 800-842-5357)
To determine specific deadlines for maintaining your health or assistance, it is important to understand the conditions surrounding Premera Blue Cross. There may be important dates for filing a claim or for becoming covered by the policy. This information can be obtained without cost. Call 800-722-1471 (TTY: 800-842-5357).

 natuurlijke leesvorm: 

Om specifiek termijnen te bepalen voor het onderhouden van uw gezondheid of hulp, is het belangrijk om te begrijpen de omstandigheden rondom Premera Blue Cross. Er zijn mogelijk belangrijke termijnen voor het indienen van een claim of worden behandeld door de beleidsvoorschriften. Deze informatie kan worden verkregen zonder kosten. Bel 800-722-1471 (TTY: 800-842-5357).

Bahasa Melayu (Malay): 


Polski (Polish): 


Português (Portuguese): 

Este aviso contém informações importantes. Este aviso poderá conter informações importantes a respeito da sua aplicação ou cobertura por meio do Premera Blue Cross. Poderão existir dados importantes neste aviso. Talvez seja necessário que você tome providências dentro de determinados prazos para manter sua cobertura de saúde ou 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).

Romania (Romanian): 


Русский (Russian): 

Настоящее уведомление содержит важную информацию. Это уведомление может содержать важную информацию о вашем заявлении или страховом покрытии через Premera Blue Cross. В настоящем уведомлении могут быть указаны ключевые даты. Вам, возможно, потребуется принять меры к определенным предельным срокам для сохранения страхового покрытия или помощи с расходами. Вы имеете право на бесплатное получение этой информации и помощь на вашем языке. Звоните по телефону 800-722-1471 (TTY: 800-842-5357).

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

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Ang Pakawala na ito ay naglalaman ng mahalagang impormasyon. Ang pakawala na ito ay naglalaman ng mahalagang impormasyon tungkol sa iyong aplikasyon o pagkakasap sa pamamagitan ng Premera Blue Cross. Maaaring may mga mahalagang paksin dito sa pakawala na ito. Maaaring magalaingan ka na magsagawa ng hakbang sa ilang mga itinakdang hakbang sa ilang mga itinakdang hakbang. 800-722-1471 (TTY: 800-842-5357).