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

RELATED MEDICAL POLICIES:
2.01.38 Transesophageal Endoscopic Therapies for Gastroesophageal Reflux Disease
2.01.91 Peroral Endoscopic Myotomy (POEM) 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

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

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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. 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 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>Ongoing</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>NCT02505945</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>
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<tr>
<td>NCT01940185&lt;sup&gt;a&lt;/sup&gt;</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

<sup>a</sup> 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.<sup>19</sup> 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.<sup>20</sup> 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

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<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>
</tr>
<tr>
<td>01/30/14</td>
<td>Update Related Policies. Change title to 2.01.38.</td>
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### Comments

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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 &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>
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<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>
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<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>
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<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>
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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.
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  - Information written in other languages

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Toll free 855-332-4535, Fax 425-918-5592, TTY 800-842-5357
Email AppealsDepartmentinquines@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 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).

عربي (Arabic):
لا يوجد في هذا الإشعار معلومات هامة. قد يحتوي هذا الإشعار معلومات هامة يتعين على مراجعتها. 
Premera Blue Cross. تتم مراجعتها على هذه المعلومات والمعلومات المعلقة بهم، 
800-722-1471 (TTY: 800-842-5357) للإجابة.

Oromoo (Cushite):
Beeksinsi kun odedefanoon bbaarbachaasaa qaba. Beekisti kun sagantaa 
yooyan kaaraa Premera Blue Cross tiin tajajila keessan ilaaachise 
neebeebarbachaasaa qabaachu danda’a. Guyyaawann murteeesaa 
taan beekisita kana keessatti ilaaalaa. Tarii kaffaltii daan deegarmuuf 
yooyan tajajilaa fayyaa keessanint guyyaaw dhumaa iratti wanti rawwattan 
jaachu danda’a. Kaffaltii iraa bilisa haala ta’aen afaan keessanin 
neebeebarbachaasaa argachu fi deegarsaa argachuq miga ni qabatuut. 
Lakkoofsa bibiila 800-722-1471 (TTY: 800-842-5357) ti bibiila.

Français (French):
Appelez le 800-722-1471 (TTY: 800-842-5357).

Kreyòl ayisyen (Creole):
Avi sila a gen Enmòsìm Enpòtan Iadann. Avi sila a kapab genyen 
enfòmasyon enpòtan konsènsan aplikasyon w lan osawa konsèn 
kvòtìa asirans lan atravé Premera Blue Cross. Kapab genyen dat ki en 
pòtan an avi sila a. Ou ka gen pou pran kék askyon avan seten dat limit pou 
ka beke kvòtìa asirans sante w la osawa pou yo ka ede w avèk depans yo. 
Se dwa w pou resewa enfòmasyon sa a ak assistans nan lang ou pale a, 
san ou pa gen pou peye pou sa. Rate nan 800-722-1471 
(TTY: 800-842-5357).

Deutsche (German):

Hmoob (Hmong):
Tsaab ntaaw tshaj xo no muaj cov ntsiab lus tseem ceeb. Tey zaum 
tsaab ntaaw tshaj xo no muaj cov ntsiab lus tseem ceeb tsoog kog daim 
sawt thov kev pab los yog kog qho kev pab cuam los ntaaw Premera Blue Cross. Tey zaum muaj cov hunb tseem ceeb cuam saw rau hauv daim ntaaw no. Tey taam kog juy yuav tau uu qee yam uu pas koh kog uu taas pub 
hau cov cajy nyong uas teev tseeg rau hauv daim ntaaw no mas kog juy 
yuav tau basa kev pab cuam kho mob los yog kev pab tem tej nqi kho mob 
ntawd. Kog muaj cui kom lawv muab cov ntsiab lus no uas tau muab sau 
ku kog hom lus pub dawb rau kog. Hu rau 800-722-1471 
(TTY: 800-842-5357).

Ilokõ (Ilocano):
Daytoy a Pakdaa ket naglaon iti Napatement nga Impormasion. Daytoy a 
pakdaa mabalit nga adda ket naglaon iti napatement nga impormasion 
maipangeep iti aplikasyon weny trong coverage babaen iti Premera Blue Cross. Daytoy ket mabalit dagiti importante a pelta iti daytoy a pakdaa. 
Mabalit nga adda rumbeng nga aramidengo nga addang sakyay dagiti 
partikular a naituding nga aldaw tapno mapagtalainedyo ti coverage ti 
salun-atyo wenno tulong kadagiti gastos. Adda karbenganyo a mangala iti 
daytoy nga impormasion ken tulong iti bukodyo a pagasasao nga awan ti 

Italiano (Italian):
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 
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Punjabi (Punjabi): ਨੋਵਾਂ ਅਪਨਾ ਨਿਊਜ਼ ਦਾ ਸ਼ਬਦਕਾਰ ਹੈ Premera Blue Cross ਨੇ ਇੱਥੇ ਦਿਨਾਂ ਦੌਰਾਣ ਅਲੋਏ ਤਰਕਾਲਾ ਦੇ ਸ਼ਬਦਕਾਰ ਹੈ। ਹਾਂ, ਸਿਰਫ ਸਚ ਦਾ ਕਰਨ ਦੁਆਰਾ ਸਚ ਥੋਂ ਵਧਾਏ ਕਿੱਤਾ। ਸ਼ਬਦਕਾਰ ਤੇਰੀ ਰਾਹ ਲਈ, ਇੱਥੇ ਦਿਨਾਂ ਦੌਰਾਣ ਅਲੋਏ ਤਰਕਾਲਾ। 


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Samoan (Samoan): Fa’aasamoa (Samoa): Atoua ua i ai i lelei fa’asilasiaga ni fa’amatala e sili ona tauta e tauta ona e malamalama i ai. O lelei fa’asilasiaga o se fa’asoaoni e fa’amatala attu i ai. Fa’amoleme, ia i e foi o lelei fa’alelei i o fa’ai o lelei fa’asilasiaga tauta. Masolo o lelei ai ni fa e tauta ona e faiafo a ti ai a lea e a lea aleo ia lea aso ua i ai i lelei fa’asilasiaga ina i ai e i nei mai ma fa malamo fa’asoaoni mai ai i lelei fa’asilasiaga tautha. O lo i ai i o lelei fa’asilasiaga ina i ai e i nei mai ma fa malamo fa’asoaoni mai ai i lelei fa’asilasiaga tauta. Malamo o lelei ai ni fa e tauta ona e faiafo a ti ai a lea e a lea aleo ia lea aso ua i ai i lelei fa’asilasiaga ina i ai e i nei mai ma fa malamo fa’asoaoni mai ai.

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