**Title:** LINX™ Reflux Management System  
**Policy #:** MN.012.B  
**Type:** Medical  
**Sub-Type:** Medical Necessity (MN)

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**PRODUCT VARIATIONS**

This policy applies to all HealthPartners Plans (HPP) product lines unless noted below.

☒ Medicare Variation

For details regarding Medicare's position of not medically necessary please refer to the following:

- Related Local Coverage Determination
- LCD L35094 Services That Are Not Reasonable and Necessary

Where Medicare coverage documents address services/conditions, they supersede this policy.

*NOTE: This policy only applies when a specific HPP medical necessity policy addressing the item/service does not exist. For Medicare products, Medicare guidance documents (Internet-only manuals, national and local coverage determinations) supersede this policy.*

**POLICY STATEMENT**

An implantable magnetic esophageal ring used to treat gastroesophageal reflux disease (GERD). The LINX™ Reflux Management System is considered experimental/investigational and, therefore, not covered because the safety and/or effectiveness of this service cannot be established by review of the available published peer literature.

**POLICY GUIDELINES**

N/A
CODING

The Current Procedural Terminology (CPT®), Healthcare Common Procedure Coding System (HCPCS), and the 10th revision of the International Statistical Classification of Diseases and Related Health Problems (ICD-10) codes that may be listed in this policy are for reference purposes only. Listing of a code in this policy does not imply that the service is covered and is not a guarantee of payment. Other policies and coverage guidelines may apply. When reporting services, providers/facilities should code to the highest level of specificity using the code that was in effect on the date the service was rendered. This list may not be all inclusive.

<table>
<thead>
<tr>
<th>CPT Code</th>
<th>Description</th>
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<tr>
<td>43284</td>
<td>Laparoscopy, surgical, esophageal sphincter augmentation procedure, placement of sphincter augmentation device (i.e., magnetic band), including cruroplasty when performed</td>
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*CPT® is a registered trademark of the American Medical Association.*

<table>
<thead>
<tr>
<th>ICD-10 Code</th>
<th>Description</th>
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<td>N/A</td>
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BENEFIT APPLICATION

Medical policies do not constitute a description of benefits. This medical necessity policy assists in the administration of the member’s benefits which may vary by line of business. Applicable benefit documents govern which services/items are eligible for coverage, subject to benefit limits, or excluded completely from coverage. This policy is invoked only when the requested service is an eligible benefit as defined in the Member’s applicable benefit contract on the date the service was rendered. Services determined by the Plan to be investigational or experimental are excluded from coverage for all lines of business. For Medicaid members under 21 years old, benefits and coverage are always based on medical necessity review.

DESCRIPTION OF SERVICES

This policy describes considerations in determining when services are experimental/investigational. 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 10-20% 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 possible 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.

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.

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.

**CLINICAL EVIDENCE**

According to the *American College of Gastroenterology 2017 Clinical Practice Guidelines*, sphincter augmentation using the LINX™ Reflux system constructed of titanium beads has been shown to be effective in reducing the amount of pathologic esophageal acid exposure in a small number of subjects (n=99) for up to 4 years. This device has been approved by the FDA based on a clinical study in 100 GERD patients. This study found that implantation of LINX™ resulted in consistent symptom relief and pH control with markedly fewer side effects than traditional laparoscopic fundoplication in well-selected patients. However, more data are required before widespread usage can be recommended. (1)

Loh et al (2014) examined if the LINX™ reflux management system is an effective treatment for patients with symptoms of GERD not controlled by proton pump inhibitors (PPI). A total of 48 LINX-related papers were identified using the reported search, of which 3 represented the best evidence to answer the clinical question. The authors, journal, date and country of publication, patient group, study type, relevant outcomes and results of these papers were tabulated. All 3 studies were prospective case studies. They demonstrated that LINX™ is an effective treatment for GERD patients with good short- and medium-term outcomes and an acceptable safety profile. The authors concluded that further studies are needed to determine its long-term outcomes and its relative efficacy as compared to other established treatments. (5)

An assessment by the ECRI Institute (2013) of the LINX™ procedure judged the quality of studies to be low. Commenting on the pivotal studies by Ganz, et al., and Lipham, et al., the ECRI report stated that weaknesses of these studies include inconsistent and incomplete results reporting (Ganz et al. reported intent-to-treat [ITT] at one year, not at subsequent follow-ups, patients were lost to follow-up; Lipham reported findings on the basis of patients lost to follow-up, not ITT), and post-hoc analyses on an unclear number of patients. Both studies took baseline esophageal pH level measurements while patients were off PPI therapy, so no pre-post pH comparison data for PPI therapy and LINX™ are available. The ECRI reported also noted that results in the text of articles did not consistently correspond to results in tables. (2)

Ganz et al (2013) prospectively assessed 100 patients with GERD before and after sphincter augmentation. The study did not include a concurrent control group. The primary outcome measure was normalization of esophageal acid exposure or a 50 % or greater reduction in exposure at 1 year. Secondary outcomes were 50 % or greater improvement in quality of life related to GERD and a 50 % or greater reduction in the use of PPIs at 1 year. For each
outcome, the pre-specified definition of successful treatment was achievement of the outcome in at least 60 % of
the patients. The 3-year results of a 5-year study were reported. The primary outcome was achieved in 64 % of
patients (95 % CI: 54 to 73). For the secondary outcomes, a reduction of 50 % or more in the use of PPIs occurred in
93 % of patients, and there was improvement of 50 % or more in quality-of-life scores in 92 %, as compared with
scores for patients assessed at baseline while they were not taking PPIs. The most frequent adverse event was
dysphagia (in 68 % of patients post-operatively, in 11 % at 1 year, and in 4 % at 3 years). Serious adverse events
occurred in 6 patients, and in 6 patients the device was removed. The authors concluded that the current study was
designed so that the direct effects of the sphincter augmentation device on each patient's exposure to esophageal
acid, use of PPIs, and symptom control could be measured before and after the implantation. This design was
limited in that it did not allow direct comparisons with other forms of therapy. These researchers stated that
prospective, randomized trials with larger samples and longer-term follow-up are needed to confirm these early
results and assess longer-term safety. (3)

In a multi-center, prospective, single-arm study, Lipham et al (2012) examined the long-term safety and
effectiveness of the LINX™ reflux management system. A total of 44 patients underwent a laparoscopic surgical
procedure for placement of the LINX™ System around the gastro-esophageal junction (GEJ). Each patient’s baseline
GERD status served as the control for evaluations post-implant. Long-term efficacy measures included esophageal
acid exposure, GERD quality-of-life measures, and use of PPIs. Adverse events and long-term complications were
closely monitored. For esophageal acid exposure, the mean total % time pH less than 4 was reduced from 11.9 % at
baseline to 3.8 % at 3 years (p < 0.001), with 80 % (18/20) of patients achieving pH normalization (less than or equal
to 5.3 %). At greater than or equal to 4 years, 100 % (23/23) of the patients had improved quality-of-life measures
for GERD, and 80 % (20/25) had complete cessation of the use of PPIs. There have been no reports of death or long-
term device-related complications such as migration or erosion. The authors concluded that sphincter augmentation
with the LINX™ Reflux Management System provided long-term clinical benefits with no safety issues, as
demonstrated by reduced esophageal acid exposure, improved GERD-related quality of life, and cessation of
dependence on PPIs, with minimal side effects and no safety issues. Patients with inadequate symptom control with
acid suppression therapy may benefit from treatment with sphincter augmentation. The major drawbacks of this
study were its small sample size (only 23 patients were available at 4 years) and the lack of a comparison group. (4)

Food and Drug Administration (FDA)

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 maximum therapy for the treatment of reflux. FDA has required 5-year follow-
up of 100 patients from the investigational device exemption pivotal study to evaluate safety and efficacy of the
device. FDA product code: LEI.
POLICY HISTORY

This section provides a high-level summary of changes to the policy since the previous version.

<table>
<thead>
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<th>Summary</th>
<th>Version</th>
<th>Version Effective Date</th>
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<td>Annual policy review and re-issue. No revisions to this version.</td>
<td>B</td>
<td>12/1/2018</td>
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<tr>
<td>N/A – This is a new policy bulletin.</td>
<td>A</td>
<td>6/30/2017</td>
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REFERENCES


