Preauthorization is required.

The following protocol contains medical necessity criteria that apply for this service. The criteria are also applicable to services provided in the local Medicare Advantage operating area for those members, unless separate Medicare Advantage criteria are indicated. If the criteria are not met, reimbursement will be denied and the patient cannot be billed. Please note that payment for covered services is subject to eligibility and the limitations noted in the patient’s contract at the time the services are rendered.

RELATED PROTOCOL
Transesophageal Endoscopic Therapies for Gastroesophageal Reflux Disease

<table>
<thead>
<tr>
<th>Populations</th>
<th>Interventions</th>
<th>Comparators</th>
<th>Outcomes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Individuals: • With gastroesophageal reflux disease</td>
<td>Interventions of interest are: • Magnetic sphincter augmentation</td>
<td>Comparators of interest are: • Continued medical therapy • Laparoscopic fundoplication</td>
<td>Relevant outcomes include: • Symptoms • Change in disease status • Medication use • Treatment-related morbidity</td>
</tr>
</tbody>
</table>

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.

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 of-
ten comparing MSA with laparoscopic Nissen fundoplication, generally have shown that GERD-health-related quality of life 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 non-randomized, may be affected by selection bias, and the subjective outcome measures used in these studies (e.g., the GERD-health-related quality of life scores) may be biased. Randomized comparisons of MSA with laparoscopic Nissen fundoplication are needed to evaluate the relative risk-benefit of these two procedures. Although the evidence is insufficient to determine the superiority of MSA when compared with laparoscopic Nissen fundoplication, the available evidence suggests these procedures are similar in both short and long term effectiveness as well as comparative safety. Therefore, the evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

POLICY

Magnetic esophageal sphincter augmentation (MSA) to treat gastroesophageal reflux disease is medically necessary for patients with persistent and documented GERD when the following criteria are met:

- There is a failure of medical management, including lifestyle changes and a trial of maximum medical therapy, OR
- There is intolerance to medical therapy, AND
- MSA is proposed rather than laparoscopic Nissen fundoplication.

BACKGROUND

GASTROESOPHAGEAL REFLUX DISEASE

GERD is defined as the 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.

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 a five-year follow-up of 100 patients from the investigational device exemption pivotal study to evaluate the safety and efficacy of the device, which was completed in March 2016. Food and Drug Administration product code: LEI.

Services that are the subject of a clinical trial do not meet our Technology Assessment and Medically Necessary Services Protocol criteria and are considered investigational. For explanation of experimental and investigational, please refer to the Technology Assessment and Medically Necessary Services Protocol.

It is expected that only appropriate and medically necessary services will be rendered. We reserve the right to conduct prepayment and postpayment reviews to assess the medical appropriateness of the above-referenced procedures. Some of this protocol may not pertain to the patients you provide care to, as it may relate to products that are not available in your geographic area.
REFERENCES

We are not responsible for the continuing viability of website addresses that may be listed in any references below.


