



Subject: LINX Reflux Management System

Revision Date: 3/25

DESCRIPTION

According to the LINX® Reflux Management System Important Safety Information, the LINX® Reflux Management System is a laparoscopic, fundic-sparing anti-reflux procedure indicated for patients diagnosed with Gastroesophageal Reflux Disease (GERD) as defined by abnormal pH testing, and who are seeking an alternative to continuous acid suppression therapy (i.e. proton pump inhibitors or equivalent) in the management of their GERD.

APPLICABILITY

This policy applies to all OSU Health Plan (OSUHP) benefit plans.

DEFINITIONS

Gastroesophageal Reflux Disease (GERD): The Montreal consensus defined GERD as “a condition which develops when the reflux of stomach contents causes troublesome symptoms and/or complications.”

POLICY

OSU Health Plan considers magnetic sphincter augmentation using the LINX® Reflux Management System medically necessary when all of the following criteria are met:

1. 18 years of age or older; and
2. Abnormal pH testing in which acid exposure time (AET) is greater than 6% on 24-hour pH monitoring; and
3. Normal esophageal motility on manometric evaluation; and
4. Patient has undergone appropriate endoscopic evaluation to rule out

extragastrointestinal etiology of symptoms

5. Symptoms are moderate-to-severe according to a validated questionnaire or assessment tool (i.e., Foregut Symptom Questionnaire, Reflux Disease Questionnaire [RDQ], GERD-Health Related Quality of Life [GERD-HRQL]); and
6. Symptoms persist for at least 6 months despite maximal medical therapy, including all of the following:
 - a. Lifestyle changes:
 - i. Weight loss for patients with GERD who are overweight or have had recent weight gain
 - ii. Dietary changes (avoiding trigger foods, managing meal size and timing, etc.)
 - iii. Elevation of the head of the bed in individuals with nocturnal or laryngeal symptoms (e.g., cough, hoarseness, throat clearing)
 - b. Proton Pump Inhibitors once or twice a day for a minimum of 2 months, such as:
 - i. Omeprazole 20 mg
 - ii. Lansoprazole 30 mg
 - iii. Esomeprazole 20 mg
 - iv. Pantoprazole 40 mg
 - v. Dexlansoprazole 30 mg
 - vi. Rabeprazole 20 mg

Removal of the LINX® Reflux Management System is medically necessary for complications or failure of treatment

PROCEDURE

Based on the available literature, the majority of patients are discharged home post-operatively within 24 – 48 hours. Therefore, if the above criteria are met, magnetic sphincter augmentation will be approved as an outpatient surgery.

Prior authorization requests should include the following medical records for review:

- Progress notes documenting symptoms, conservative treatment (including specific lifestyle changes; medication name(s), dose(s), length of trial with dates), BMI, etc.
- Questionnaires/Assessment tools (i.e., Foregut Symptom Questionnaire, Reflux Disease Questionnaire [RDQ], GERD-Health Related Quality of Life [GERD-HRQL])
- Upper endoscopy
- Esophageal pH testing
- Esophageal manometry
- Barium esophagram

PRIOR AUTHORIZATION

The LINX procedure always requires prior authorization.

EXCLUSIONS

OSU Health Plan considers the LINX® Reflux Management System contraindicated or experimental for the following indications (not all-inclusive):

- Suspected or known allergy to titanium, stainless steel, nickel, or ferrous materials
- Barrett's esophagus
- Grade C or D esophagitis (LA classification)
- Electrical implants (pacemakers and defibrillators) or other metallic abdominal implants
- Major motility disorders
- Scleroderma
- Suspected or confirmed esophageal or gastric cancer
- Distal esophageal motility less than 35 mmHg peristaltic amplitude on wet swallows, < 70% (propulsive) peristaltic sequences, or known motility disorder such as Achalasia, Nutcracker Esophagus, Diffuse Esophageal Spasm, or Hypertensive LES
- Symptoms of dysphagia more than once per week within the last 3 months
- Esophageal stricture or gross esophageal anatomic abnormalities (Schatzki's Ring, obstructive lesions, etc.)

- Esophageal or gastric varices
- Pregnancy
- Age < 18

CODES

The following codes are covered when the above criteria are met.

Code	Code Description
43284	Laparoscopy, surgical, esophageal sphincter augmentation procedure, placement of sphincter augmentation device (ie, magnetic band), including cruroplasty when performed
43285	Removal of esophageal sphincter augmentation device

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