



Endoscopic Procedures and Non-Endoscopic Devices for Gastroesophageal Reflux Disease

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P&P # C.5.27

Policy

This Medical Policy does not constitute medical advice. When deciding coverage, the enrollee's specific plan document must be referenced. The terms of an enrollee's plan document (Certificate of Coverage (COC) or Summary Plan Description (SPD)) may differ from this Medical Policy. In the event of a conflict, the enrollee's specific benefit plan document supersedes this Medical Policy. All reviewers must first identify enrollee eligibility, any federal or state regulatory requirements, and the plan benefit coverage prior to use of this Medical Policy. Other Policies and Coverage Determination Guidelines may apply. Quartz reserves the right, in its sole discretion, to modify its Policies and Guidelines as necessary.

Procedure

A. Documentation Required:

In order to facilitate the authorization process for the LINX® Reflux Management System, referral requests must include **ALL** the following:

1. Member must be under the care of a board-certified Gastroenterologist or General Surgeon or an advance practice professional in collaboration with or supervised by a board certified Gastroenterologist or General Surgeon.
2. The General Surgeon placing the device must be certified to perform the LINX® procedure.
3. Documentation of patient symptoms and degree of functional impairment.
4. Documentation of failed conservative measures and alternative treatment including previous procedures done to treat GERD.

B. Criteria for Medical Necessity:

The LINX® Reflux Management System is considered medically necessary for patients with refractory gastroesophageal reflux when **ALL** of the following criteria are met:

- a. Must be ≥ 21 years or < 75 years of age; **AND**
- b. Must be able to undergo general anesthesia and laparoscopic surgery; **AND**
- c. Documented refractory gastroesophageal reflux disease (GERD) for > 6 months including a history of daily proton pump inhibitor (PPI) for ≥ 6 months; **AND**
- d. Documentation of a current history and physical and completion of **ALL** of the following procedures:
 - i. Esophagogastroduodenoscopy; **AND**
 - ii. Barium esophagram; **AND**
 - iii. Esophageal manometry; **AND**

- iv. 48-hour Bravo™ procedure or a 24-hour pH study with or without impedance; **AND**
- v. Must have abnormal pH testing off acid suppression defined as a pH of less than 4 for > 4.5% of the time or a Demeester score > 14.7; **AND**
- vi. Negative pregnancy test within one week prior to implant in pre-menopausal women.

This policy approves one LINX® Reflux Management System device per lifetime when medical policy criteria are met.

C. Indications Considered Experimental and Investigational for the LINX® procedure (*Not an all-inclusive list*):

- a. LINX® as an emergency procedure;
- b. History of gastroesophageal surgery, anti-reflux procedures, or gastroesophageal/gastric cancer;
- c. Previous endoscopic anti-reflux intervention for GERD and/or previous endoscopic intervention for Barrett's esophagus;
- d. Current suspected or confirmed esophageal or gastric cancer;
- e. Distal esophageal motility less than 35 mmHg peristaltic amplitude on wet swallows or < 70% peristaltic sequences;
- f. Grade D esophagitis (despite treatment with PPI);
- g. BMI > 35;
- h. Symptoms of dysphagia more than once per week within the past 3 months;
- i. Diagnosis of scleroderma or esophageal motility disorder;
- j. Known untreated esophageal stricture or gross esophageal anatomic abnormalities;
- k. Esophageal or gastric varices;
- l. Barrett's esophagus greater than 3 cm;
- m. Pregnancy or nursing;
- n. Uncontrolled psychiatric disorder (excluding depression);
- o. Allergy to titanium, nickel, stainless steel or ferrous materials;
- p. Electrical implant or metallic abdominal implants.

D. Procedures Considered Experimental, Investigational, or not Medical Necessity for treatment of GERD (*Not an all-inclusive list*):

- a. The Medigus Ultrasonic Surgical Endostapler or MUSE system;
- b. Transesophageal radiofrequency therapy (the Stretta procedure);
- c. Endoscopic submucosal implantation of polymethylmethacrylate (PMMA) microbeads;
- d. Endolumenal gastroplasty/gastroplication (Not an all-inclusive list);
 - i. Bard ®EndoCinch™ Suturing System
 - ii. Surgical Endoscopic Plication System (EPS)
 - iii. EsophyX®System with SerosaFuse®
- e. Transoral Incisionless Fundoplication (TIF);
- f. Esophageal sphincter augmentation/implantation procedures which involves injection of inert polymer material into the submucosa of the proximal lower esophageal sphincter zone to provide bulking support to the sphincter;

g. Implanted antireflux prosthesis procedures.

CPT CODES:

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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