THE OHIO STATE UNIVERSITY
HEALTH PLAN

Subject: LINX Reflux Management System

Effective Date: 12/20
Revision Date: 9/22

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.

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 GUIDELINES

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. Increased esophageal acid exposure on 24-hour pH monitoring; and
3. Normal esophageal motility; and
4. 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
5. 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.

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

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

CODES

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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