



## MEDICAL POLICY STATEMENT OHIO MEDICAID

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06/28/2016	11/01/2018	11/01/2017
Policy Name		Policy Number
Minimally Invasive Gastroesophageal Reflux Disease (GERD) Treatment		MM-0055
Policy Type		
MEDICAL	Administrative	Pharmacy
		Reimbursement

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## A. SUBJECT

### **Gastroesophageal Reflux Disease (GERD) Treatment**

## B. BACKGROUND

Gastroesophageal reflux disease (GERD) also known as reflux esophagitis is a complex disorder resulting from multiple contributing factors, including acid production, lower esophageal sphincter tone and location, and anatomic barriers to reflux. GERD is a common problem that affects approximately 18% to 28% of the adult population with at least 20% of Americans reporting weekly symptoms. The postliminary risks of esophagitis, esophageal stricture, Barrett esophagus, and adenocarcinoma of the esophagus are significant causes for concern, and justify effective therapy for patients with GERD. Treatments for GERD are designed to improve the function of the lower esophageal sphincter (LES) including eliminating symptoms, healing esophagitis and preventing recurrence of symptoms or progression of disease. Treatment for GERD may include lifestyle changes (e.g., elevating the head of the bed, decreasing fat intake, quitting smoking, diet), pharmacological therapy (e.g., acid suppressants) or anti-reflux surgery. The majority of GERD cases are controlled with medication therapy.

For patients who choose not to continue on medication therapy long term, anti-reflux surgery may be an option. An open or laparoscopic Nissen fundoplication is considered the standard surgical therapy, but some patients are not considered good candidates for surgery or invasive procedures due to the associated risks. As a result, minimally invasive procedures, including endoscopic or endoluminal therapies and laparoscopic approaches, have been suggested as alternative treatment methods to improve the function of the lower esophageal sphincter (LES), with the goal of eliminating symptoms, healing esophagitis, preventing recurrence of symptoms or progression of disease, and reducing the need for lifelong pharmacologic therapy. They may be classified into 3 basic categories: (1) endoscopic or plication suturing of the proximal stomach; (2) radiofrequency (RF) energy delivered to the GEJ; and (3) polymer injection or implantation of bulking agents into the cardia or distal esophagus

#### **American Society of General Surgeons (ASGS)**

The American Society of General Surgeons (ASGS) issued a position statement on transoral fundoplication in 2011 stating that “ASGS supports the use of transoral fundoplication by trained General Surgeons for the treatment of symptomatic chronic gastroesophageal reflux disease (GERD) in patients who fail to achieve satisfactory response to a standard dose of Proton Pump Inhibitor (PPI) therapy or for those who wish to avoid the need for a lifetime of medication dependence.”

#### **The American Gastroenterological Association (AGA)**

The American Gastroenterological Association (AGA) offer a *Grade A* recommendation for antireflux surgery: “When antireflux surgery and PPI therapy are judged to offer similar efficacy in a patient with an esophageal GERD syndrome, PPI therapy should be recommended as initial therapy because of superior safety. When a patient with an esophageal GERD syndrome is responsive to, but intolerant of, acid suppressive therapy, antireflux surgery should be recommended as an alternative.”

The **AGA** Medical Position Statement on the Management of Gastroesophageal Reflux Disease states that due to insufficient information they can make no recommendation for or against the use of currently commercially available endoluminal antireflux procedures in the management of patients with an esophageal syndrome.

### **The American Society for Gastrointestinal Endoscopy (ASGE)**

The American Society for Gastrointestinal Endoscopy (ASGE) does not recommend the use of the only two endoluminal GERD therapies being used in the United States: the Stretta procedure and the Transoral Incisionless Fundoplication (TIF) (EsophyX device), but suggests that endoscopic antireflux therapy be considered for selected patients with uncomplicated GERD after careful discussion with the patient regarding potential adverse effects, benefits, and other available therapeutic options.

### **American College of Gastroenterology (ACG)**

The American College of Gastroenterology published practice guidelines in 2013 regarding the diagnosis and management of GERD, stating: "usage of current endoscopic therapy or transoral incisionless fundoplication cannot be recommended as an alternative to medical or traditional surgical therapy."

### **Society of American Gastrointestinal and Endoscopic Surgeons (SAGES)**

The Society of American Gastrointestinal and Endoscopic Surgeons (SAGES) updated published clinical guidelines in 2017 regarding endoluminal treatments for GERD and issued a statement: "Based on existing evidence, Transoral Incisionless Fundoplication TIF can be performed with an acceptable safety risk in appropriately selected patients. The procedure leads to better control of GERD symptoms compared with PPI treatment in the short term (6 months), but appears to lose effectiveness during longer term follow-up and is associated with moderate patient satisfaction scores. Objective GERD measures improve similarly after TIF 2.0 compared with PPI. No comparative, controlled trials exist between TIF and surgical fundoplication, but preliminary evidence suggests that the latter can be used safely after TIF failure." In that same update, the following is stated: "Based on existing evidence, Stretta significantly improves health related quality of life score, heartburn scores, the incidence of esophagitis, and esophageal acid exposure in patients with GERD, but does not increase lower esophageal sphincter basal pressure. In addition, it decreases the use of PPI by approximately 50%. The effectiveness of the procedure diminishes some over time, but persistent effects have been described up to 10 years after the procedure in appropriately selected patients with GERD. Stretta is more effective than PPI, but less so than fundoplication. Stretta is safe in adults and has a short learning curve."

## **C. DEFINITIONS**

- **Radiofrequency Energy/Stretta:** Low-power, low-temperature RF energy to the lower esophageal sphincter (LES) muscle and gastric cardia remodels the tissue to thicken the musculature and increase the size and amount of smooth muscle fibers for better barrier function and fewer transient LES relaxations.
- **Endoscopic Plication or Suturing:** The Bard EndoCinch and the Endoscopic Suturing Device (ESD), involves endoscopic suturing, allows for the placement of proximal to the LES, and the NDO Endoscopic Plication System, also known as the NDO Plicator System, places a full-thickness transmural plication near the gastroesophageal junction under direct endoscopic visualization. The EsophyX System: Uses transoral incisionless fundoplication (TIF) to recreate a barrier to reflux, retracting the tissue at the Z line (esophagus and stomach junction) and attaching fasteners 1 cm above the Z line for a 270° valve of 2 to 3 cm in length.
- **Injection or Implantation:**
  - Magnetic Sphincter Augmentation (MSA) for the treatment of GERD uses a surgical device (LINX Reflux Management System) as a minimally invasive alternative to fundoplication. The MSA device consists of an expandable, circumferential bracelet of magnetic titanium beads linked together by independent titanium wires. When implanted around the distal esophagus at the gastroesophageal junction, magnetic forces attract the beads to each other, holding the junction closed.
  - The Plexiglas (polymethylmethacrylate [PMMA]) procedure involves injection of an inert polymer material into the submucosa of the proximal lower esophageal sphincter zone to

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- provide bulking support to the sphincter and decrease transient relaxation of the lower esophageal sphincter (tLESRs).
- The Gatekeeper Reflux Repair System utilizes a soft, pliable, expandable prosthesis made of a polyacrylonitrile-based hydrogel. The prosthesis is implanted into the esophageal submucosa, and with time, the prosthesis absorbs water and expands, creating bulk in the region of implantation. These agents are not commercially available in the United States.
  - Another bulking agent, pyrolytic carbon-coated beads (Durasphere®), is being evaluated for treatment of GERD. Durasphere is approved by the U.S. Food and Drug Administration (FDA) as a submucosal urethral bulking agent. Application of this product for esophageal reflux would be considered off-label use.
  - LINX Reflux Management System is a device used for Magnetic Sphincter Augmentation. The LINX System consists of a band of interlinked titanium beads with magnetic cores. The magnetic attraction helps the lower esophageal sphincter (LES) resist opening to gastric pressures, thus preventing reflux. The act of swallowing temporarily breaks the magnetic bond and allows food and liquid to pass normally into the stomach.

## D. POLICY

- I. The safety and efficacy of endoscopic therapies for the treatment of GERD have not been established in the published medical literature. Current studies are generally of small to moderate size, lack adequate control or comparison groups, and provide only short-term follow-up. Well-designed clinical trials with long-term follow up are required to establish that endoscopic therapies benefit health outcomes in patients with GERD by eliminating symptoms, preventing recurrence of symptoms or progression of disease, healing esophagitis, and reducing or eliminating the need for pharmacologic therapy.
- II. Endoscopic therapies are unproven and not medically necessary for the treatment of gastroesophageal reflux disease (GERD).
  - A. Endoscopic therapies include:
    1. Radiofrequency energy
      - 1.1 Stretta System
  - B. Endoscopic plication or suturing include:
    1. Bard EndoCinch Endoscopic Suturing System
    2. Endoscopic Suturing Device (ESD)
    3. Surgical Endoscopic Plication System (EPS)
    4. EsophyX™ System with SerosaFuse™ Fastener (transoral incisionless fundoplication (TIF) procedure)
  - C. Injection or implantation techniques include:
    1. Gatekeeper Reflux Repair System
    2. Plexiglas (polymethylmethacrylate [PMMA]) procedure
    3. Durasphere®
    4. LINX™ Reflux Management System

### III. Radiofrequency Energy (Stretta System)

Additional well-designed clinical trials comparing radiofrequency energy with other surgical alternatives are needed to determine the efficacy and long-term effectiveness of radiofrequency energy. The current body of evidence is of low to moderate quality with several study limitations, including lack of generalizability and lack of sufficient follow-up data. There are persistent questions regarding the safety of radiofrequency energy over the long term.

### IV. Endoscopic Plication or Suturing

The overall quality of the evidence is very low since the available studies lack adequate control or comparison groups, and have small populations, and inadequate follow-up times. Additional well-designed, independent comparative clinical trials with long-term follow-up are required to further evaluate the GERD plication procedure using the EsophyX/SerosaFuse system.

## V. Injection and Implantation Techniques

The overall quality of the evidence is very low since the available studies lack quality design, adequate controls or comparison groups and have small populations. Further research with larger patient populations are needed to determine the clinical relevance of these techniques and determine long term safety and efficacy.

## E. CONDITIONS OF COVERAGE

HCPGs  
CPT

### AUTHORIZATION PERIOD

## F. RELATED POLICIES/RULES

## G. REVIEW/REVISION HISTORY

DATES		ACTION
Date issued	06/28/2016	New Policy.
Date Revised	06/28/2017	Updated the background and references
Date Effective	11/01/2017	

## H. REFERENCES

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