

Endoscopic Procedures for the Treatment of Gastroesophageal Reflux Disease

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Developed By: Medical Necessity Criteria Committee

I. Description

Gastroesophageal reflux disease (GERD) occurs as a result of the stomach contents leaking back into the esophagus due to the improper closing of the lower esophageal sphincter (LES). The refluxed acid causes a burning sensation in the esophagus commonly called heartburn. If heartburn occurs more than two times a week, it may be considered GERD. Symptoms include heartburn, acid reflux, morning hoarseness, difficulty swallowing, dry cough and pain in the chest. Recurring GERD can cause severe damage to the esophagus. The mildest form of GERD may be controlled with lifestyle modifications or over-the-counter medications. Proton pump inhibitors (PPIs) are then used for patients who fail initial treatment. Surgery may be considered when these therapies fail. Laparoscopic fundoplication is the standard surgical method for treating GERD; however, newer, less invasive endoscopic methods are becoming more readily available. The following procedures have been investigated for the treatment and management of GERD:

Transoral Incisionless Fundoplication: Transoral Incisionless Fundoplication (TIF) performed with the EsophyX® device is an endoscopic procedure for the treatment of gastroesophageal reflux disease (GERD). The TIF procedure clinical objectives are a) to mechanically repair a defective gastroesophageal valve and b) to reduce small hiatal hernias. The goal of therapy is to control both the symptoms and mucosal damage. Based on the most recent data, the TIF procedure appears to be a valuable treatment alternative for the management of appropriately selected patients with moderate to severe chronic GERD symptoms.

Radiofrequency Energy or Radiofrequency Thermal Ablation: Thermal energy is delivered to the lower esophageal sphincter (LES) using endoscopically placed needles. Thermal lesions are produced. The mechanism of action of the thermal lesions is not known but may be related to ablation of the nerve pathways responsible for sphincter relaxation. An example of this procedure is the Stretta™ System. This system received FDA approval in 2000 for general use in the electro-surgical coagulation of tissue intended for use in the treatment of GERD.

Gastric Plication/Suturing Techniques: In these types of procedures, sutures are placed in the lower esophageal sphincter. Specifically, a needle puncture device attached to the endoscope creates pleats through a series of sutures passed by a needle through adjoining proximal fundic folds at the

gastroesophageal junction. The sutures are designed to strengthen and lengthen the sphincter in order to decrease reflux. Examples of suture plication gastroplasty devices are the EndoCinch™, Bard Endoscopic Suturing System (BESS), the Full Thickness Plicator™, and the Syntheon ARD Plicator.

Polymer Injection/Implantation Techniques: These types of procedures are known as bulking techniques. The goal is to provide bulking support to the sphincter. Bulking procedures include: endoscopic submucosal implantation of polymethylmethacrylate (PMMA) beads into the lower esophageal folds and implantation of expandable hydrogel prostheses at the gastroesophageal junction. Gatekeeper™ Reflux Repair System is an example of expandable hydrogel prosthesis.

Per-Oral Endoscopic Myotomy (POEM): *Refer to Moda Health Medical Necessity Criteria for Surgical Treatment of Achalasia*

The LINX® Reflux Management System: The laparoscopic placement of magnetic esophageal rings are considered investigational. There is insufficient evidence of randomized-controlled studies that demonstrate the long-term safety and effectiveness of laparoscopically-implanted magnetic esophageal rings.

Note: Endoscopic liquid polymer implantation (Boston Scientific Corporation) also known as Enteryx was recalled September 23, 2005 and is no longer available on the market

II. Criteria: CWQI HCS-0028A

- A. Moda Health considers **transoral incisionless fundoplication (TIF)** medically necessary when **ALL** of the following criteria are met:
- a. 18 years of age or older
 - b. Confirmed diagnosis of esophageal reflux by endoscopy, ambulatory pH, or barium swallow testing.
 - c. History of GERD symptoms for one year occurring 2 to 3 times per week.
 - d. GERD patients with body mass index (BMI) ≤ 35 .
 - e. History of daily proton pump inhibitor's (PPI's) for greater than 6 months
 - f. Absence of **ALL** of the following conditions;
 - i. Absence of a hiatal hernia or one that is 2 cm or less.
 - ii. No esophagitis LA (Los Angeles classification system) grade C or D. (*See *Classification below*)
 - iii. Barrett's esophagus, or if present it is 2 cm or less.
 - iv. Achalasia
 - v. Esophageal ulcer
 - vi. Esophageal motility disorder
 - vii. Altered esophageal anatomy preventing insertion of the device.
 - viii. No previous failed anti-reflux surgery/procedure.

B. Moda Health considers all other endoscopic procedures for the treatment and management of GERD or other disorders of the esophagus to be experimental and investigational and/or unproven. There is insufficient published scientific evidence to support the long-term effectiveness of these procedures and to show them to be as safe and effective as other options for the treatment of GERD. Endoscopic procedures that are considered experimental and investigational including but not limited to **ALL** of the following:

- a. Angelchik anti-reflux prosthesis
- b. EndoCinch™ or Bard Endoscopic Suturing System (BESS)
- c. Enteryx
- d. LINX Reflux Management System (except Medicare) – (*Laparoscopic or open surgical procedure*)
- e. StomaphyX
- f. Full-Thickness Plicator™
- g. Gatekeeper™ Reflux Repair System
- h. Plexiglas or polymethylmethacrylate implantation.
- i. Plicator System
- j. Stretta™ System
- k. Syntheon ARD Plicator

***The Los Angeles Classification of Oesophagitis:**

- Grade A:** One (or more) mucosal break no longer than 5 mm that does not extend between the tops of two mucosal folds
- Grade B:** One (or more) mucosal break more than 5 mm long that does not extend between the tops of two mucosal folds
- Grade C:** One (or more) mucosal break that is continuous between the tops of two or more mucosal folds but which involve less than 75% of the circumference
- Grade D:** One (or more) mucosal break which involves at least 75% of the esophageal circumference

III. Information Submitted with the Prior Authorization Request:

- 1. Provider records of physical exam and symptoms
- 2. Prior treatments tried
- 3. Prior medical history and surgeries/procedures related to GERD

IV. CPT or HCPC codes covered if criteria met:

Codes	Description
43210	Esophagogastroduodenoscopy, flexible, transoral; with esophagogastric fundoplasty, partial or complete, includes duodenoscopy when performed

V. CPT or HCPC codes NOT covered for above listed procedures:

Codes	Description
43201	Esophagoscopy, rigid or flexible; with directed submucosal injection(s), any substance
43236	Upper gastrointestinal endoscopy including esophagus, stomach, and either the duodenum and/or jejunum as appropriate; with directed submucosal injection(s), any substance
43257	Upper gastrointestinal endoscopy including esophagus, stomach, and either the duodenum and/or jejunum as appropriate; with delivery of thermal energy to the muscle of lower esophageal sphincter and/or gastric cardia, for treatment of gastroesophageal reflux disease
43499	Unlisted procedure, esophagus
C9724	Endoscopic full-thickness placcation in the gastric cardia using endoscopic placation system (EPS); includes endoscopy

V. Annual Review History

Review Date	Revisions	Effective Date
04/2013	Annual Review: Added table with review date, revisions, and effective date.	04/24/2013
04/03/2014	Annual Review: Added Laparoscopically implanted magnetic ring and POEM to investigational procedures	04/03/2014
02/2015	Annual Review: Added description of POEM and statement in criteria regarding other disorders of the esophagus to apply to achalasia tx with POEM	02/25/2015
03/2016	Annual Review – Added ICD-10 codes	03/23/2016
07/2017	Annual Review – removed the LINX from the list of investigational procedures.	07/01/2017
06/2018	Annual Review: added TIF- added LINX back to E&I-removed ICD-10 codes	07/01/2018

VI. References

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34. Physician Advisors

Appendix 1 – Applicable ICD-10 diagnosis codes:

Codes	Description
K21	Gastro-esophageal reflux disease
K21.9	Gastro-esophageal reflux disease without esophagitis

Appendix 1 – Centers for Medicare and Medicaid Services (CMS)

Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determination (NCD) and Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. They can be found at: <http://www.cms.gov/medicare-coverage-database/search/advanced-search.aspx>. Additional indications may be covered at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCD):

Jurisdiction(s): 5, 8	NCD/LCD Document (s):

NCD/LCD Document (s):

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	Applicable State/US Territory	Contractor
F (2 & 3)	AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ	Noridian Healthcare Solutions, LLC