Endoscopic Procedures for the Treatment of Gastroesophageal Reflux Disease (GERD)

Date of Origin: 10/2004  Last Review Date: 07/26/2023  Effective Date: 08/01/2023

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 electrosurgical 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. Hiatal hernia (unless hiatal hernia is 2 cm or less)
      ii. Esophagitis LA (Los Angeles classification system) grade C or D. (*See Classification below*)
      iii. Barrett’s esophagus
      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. Apollo OverStitch endoscopic suturing system
d. Enteryx (withdrawn from market 2007)
e. LINX Reflux Management System (except Medicare) – (Laparoscopic or open surgical procedure)
f. StomaphyX
g. Full-Thickness Plicator™
h. Durasphere
i. Gatekeeper™ Reflux Repair System
j. Plexiglas or polymethylmethacrylate implantation.
k. Endoscopic Plicator System
l. Stretta™ System
m. Syntheon ARD Plicator
n. Electrical stimulation of the lower esophageal sphincter (EndoStim)

*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 attempted
3. Prior medical history and surgeries/procedures related to GERD

IV. CPT or HCPC codes covered if criteria met:

<table>
<thead>
<tr>
<th>Codes</th>
<th>Description</th>
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<tbody>
<tr>
<td>43210</td>
<td>Esophagogastroduodenoscopy, flexible, transoral; with esophagogastric fundoplasty, partial or complete, includes duodenoscopy when performed</td>
</tr>
<tr>
<td>43659</td>
<td>Unlisted laparoscopy procedure, stomach</td>
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V. CPT or HCPC codes NOT covered for above listed procedures:

<table>
<thead>
<tr>
<th>Codes</th>
<th>Description</th>
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<tbody>
<tr>
<td>43201</td>
<td>Esophagoscopy, rigid or flexible; with directed submucosal injection(s), any substance</td>
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<tr>
<td>43236</td>
<td>Upper gastrointestinal endoscopy including esophagus, stomach, and either the duodenum and/or jejunum as appropriate; with directed submucosal injection(s), any substance</td>
</tr>
<tr>
<td>43257</td>
<td>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</td>
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<tr>
<td>43499</td>
<td>Unlisted procedure, esophagus</td>
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VI. Annual Review History

<table>
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<tr>
<th>Review Date</th>
<th>Revisions</th>
<th>Effective Date</th>
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<tr>
<td>04/2013</td>
<td>Annual Review: Added table with review date, revisions, and effective date.</td>
<td>04/24/2013</td>
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<tr>
<td>04/03/2014</td>
<td>Annual Review: Added Laparoscopically implanted magnetic ring and POEM to investigational procedures</td>
<td>04/03/2014</td>
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<tr>
<td>02/2015</td>
<td>Annual Review: Added description of POEM and statement in criteria regarding other disorders of the esophagus to apply to achalasia tx with POEM</td>
<td>02/25/2015</td>
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<tr>
<td>03/2016</td>
<td>Annual Review – Added ICD-10 codes</td>
<td>03/23/2016</td>
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<tr>
<td>07/2017</td>
<td>Annual Review – removed the LINX from the list of investigational procedures.</td>
<td>07/01/2017</td>
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<tr>
<td>06/2018</td>
<td>Annual Review: added TIF- added LINX back to E/I-removed ICD-10 codes</td>
<td>07/01/2018</td>
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<tr>
<td>07/2019</td>
<td>Annual Review: removed deleted codes, updated list of endoscopic procedures considered E/I</td>
<td>08/01/2019</td>
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<tr>
<td>07/2020</td>
<td>Annual Review: Removed Esophyx device from E/I list. Transoral Incisionless Fundoplication is performed with the Esophyx device as an endoscopic procedure for the treatment of gastroesophageal reflux disease</td>
<td>08/01/2020</td>
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<td>08/01/2021</td>
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<td>07/2023</td>
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<td>08/01/2023</td>
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VII. References

33. Physician Advisors
Appendix 1 – Applicable ICD-10 diagnosis codes:

<table>
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<tr>
<th>Codes</th>
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<tr>
<td>K21</td>
<td>Gastro-esophageal reflux disease</td>
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<tr>
<td>K21.9</td>
<td>Gastro-esophageal reflux disease without esophagitis</td>
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Appendix 2 – 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](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):

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NCD/LCD Document(s):

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