Endoscopic Therapies for Gastroesophageal Reflux Disease (GERD)
Policy Number: PG0166
Last Review: 03/22/2018

GUIDELINES
This policy does not certify benefits or authorization of benefits, which is designated by each individual policyholder contract. Paramount applies coding edits to all medical claims through coding logic software to evaluate the accuracy and adherence to accepted national standards. This guideline is solely for explaining correct procedure reporting and does not imply coverage and reimbursement.

SCOPE
X Professional
_ Facility

DESCRIPTION
Gastroesophageal reflux disease (GERD) is defined as symptoms or mucosa damage resulting from the reflux of gastric content into the esophagus. Mucosa damage can vary from none, to mild esophagitis, to more severe esophagitis, and, less commonly, Barrett's esophagus and esophageal carcinoma. The goal of therapy is to control both the symptoms and mucosal damage.

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 patients have mucosal disease, and symptoms are controlled with medical therapy. Anti-reflux surgery may be an option for patients who have failed pharmacotherapy or for those who choose not to continue on medication therapy for the long term. An open or laparoscopic Nissen fundoplication may be considered for patients and is considered the standard surgical therapy. A variety of endoscopic therapies for the treatment of GERD have been developed and proposed as alternatives to pharmacological therapy or anti-reflux surgery. Currently, there are three endoluminal approaches used to treat GERD.

Radiofrequency Energy
Radiofrequency energy for the treatment of GERD requires a special single-use catheter and radiofrequency energy generator (Stretta® System, [currently manufactured by Mederi Therapeutics, Greenwich, CT]). The procedure is generally performed using standard conscious sedation but has required general anesthesia in some patients. The possible mechanisms of action that result from radiofrequency energy are scarring or neurolysis at, or near, the gastroesophageal junction. This procedure is commonly referred to as the Stretta procedure.

Endoscopic Plication or Suturing
Endoscopic plication or suturing devices which includes, but may not be limited to, the following:
- The Muse™ System or Medigus Ultrasonic Surgery Endostapler utilizes a disposable flexible endoscope that is inserted through the mouth. The system combines a miniaturized video camera, a surgical stapler and ultrasonic sights for alignment. It has been suggested that the use of this device can help restore a normal gastroesophageal valve through anterior fundoplication via endoluminally placed staples.
- The EndoCinch™ or Bard Endoscopic Suturing System (BESS) (Bard Endoscopic Technologies, Billerica, MA) is used for endoscopic placement of suture(s) in the soft tissue of the esophagus and stomach and for the approximation of tissue for the treatment of symptomatic GERD. The EndoCinch is no longer recommended for use and the manufacturer, Bard, has discontinued the EndoCinch Suturing System.
- Endoscopic Plication™ System places a full-thickness transmural plication near the gastroesophageal junction under direct endoscopic visualization.
Transoral Incisionless Fundoplication (TIF) (e.g., EsophyX) is an endoscopic procedure which is used to supposedly construct a durable antireflux valve. Using SerosaFuse Fasteners, the LES is reportedly tightened, which reestablishes a barrier to reflux and restores the competency of the gastroesophageal junction.

Injection or Implantation Techniques

Bulking agents are substances injected under endoscopic guidance into the esophageal wall at the level of the esophagogastric junction to impede reflux. Implantable products/devices include, but may not be limited to, the following:

- Expandable hydrogel prosthesis (Gatekeeper™ Reflux Repair System; Medtronic, Inc., Minneapolis, MN). It has been reported that the device was withdrawn in late 2005 before U.S. Food and Drug Administration (FDA) approval. A European sham-controlled single-blind multicenter study randomized 118 patients into Gatekeeper or sham treatment. The study was terminated early due to a lack of efficacy.
- Plexiglas polymethylmethacrylate microspheres (PMMA). This agent is not commercially available in the United States.
- LINX™ Reflux Management System (Torax® Medical, Inc; St Paul, MN). The LINX Reflux Management System is an implant that consists of a small flexible band of interlinked titanium beads with magnetic cores. The magnetic attraction is proposed to help the lower esophageal sphincter (LES) resist opening to gastric pressures, preventing reflux from the stomach into the esophagus. A surgeon uses a laparoscopic incision to implant the device around the patient’s esophagus just above the stomach while the patient is under general anesthesia.
- Pyrolytic carbon-coated graphite beads suspended in a water-based carrier gel suitable for suspending the carbon-coated beads (Durasphere®, Carbon Medical Technologies, St Paul, MN). Durasphere is an injectable bulking agent that is being proposed in the treatment of mild-moderate GERD. A small nonrandomized study (n=10) was conducted by Ganz et al (2009). This study is the first report of Durasphere for the treatment of GERD. On the basis of the findings and limitations of this study, further investigation of this agent is warranted including large controlled studies with long-term outcomes.

POLICY

HMO, PPO, Individual Marketplace
All endoscopic therapies are non-covered for the treatment of GERD

Advantage

Radiofrequency energy (Stretta® System) (43257) & Transoral incisionless fundoplication (TIF) (e.g., EsophyX™) (43210) for GERD requires a prior authorization.

Procedures 43201, 43236, 43284 & 43285 for GERD require a prior authorization.

All other endoscopic therapies for the treatment of GERD are non-covered.

Elite/ProMedica Medicare Plan

Transoral incisionless fundoplication (TIF) (e.g., EsophyX™) (43210) for GERD requires a prior authorization.

All other endoscopic therapies for the treatment of GERD are non-covered.

COVERAGE CRITERIA

HMO, PPO, Individual Marketplace

Endoscopic therapies are unproven for the treatment of GERD and therefore non-covered.

Endoscopic therapies include but may not be all inclusive:

1. Radiofrequency energy
   - Stretta® System (43257)
2. Endoscopic plication or suturing
   - Muse™ System
   - Bard EndoCinch™ Endoscopic Suturing System
   - Endoscopic Plication™ System
   - Transoral incisionless fundoplication (TIF) (e.g., EsophyX™) (43210)
3. Injection or implantation techniques
   - Gatekeeper™ Reflux Repair System
   - Plexiglas (polymethylmethacrylate [PMMA]) procedure
   - Durasphere®
   - LINX™ Reflux Management System

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 the need for pharmacologic therapy.

**Advantage**
While there is insufficient evidence in the published medical literature to demonstrate the safety, efficacy and long-term outcomes of radiofrequency energy (Stretta® System) (43257), transoral incisionless fundoplication (TIF) (e.g., EsophyX™) (43210) and procedures 43201, 43236, 43284 & 43285 for GERD, The Ohio Department of Medicaid requires these procedures be reviewed for medical necessity. Therefore they may be covered with a prior authorization for Advantage members.

All other endoscopic therapies for the treatment of GERD are non-covered.

**Elite/ProMedica Medicare Plan**
While there is insufficient evidence in the published medical literature to demonstrate the safety, efficacy and long-term outcomes of transoral incisionless fundoplication (TIF) (e.g., EsophyX™) (43210) for GERD, The Center for Medicare & Medicaid Services requires this procedure be reviewed for medical necessity. Therefore, it may be covered with a prior authorization for Elite/ProMedica Medicare Plan members.

All other endoscopic therapies for the treatment of GERD are non-covered.

**CODING/BILLING INFORMATION**
The appearance of a code in this section does not necessarily indicate coverage. Codes that are covered may have selection criteria that must be met. Payment for supplies may be included in payment for other services rendered.

<table>
<thead>
<tr>
<th>CPT 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>43210</td>
<td>Esophagogastroduodenoscopy, flexible, transoral; with esophagogastic fundoplasty, partial or</td>
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<td></td>
<td>complete, includes duodenoscopy when performed</td>
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<td>43236</td>
<td>Upper gastrointestinal endoscopy including esophagus, stomach, and either the duodenum and/or</td>
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<td>jejenum as appropriate; with directed submucosal injection(s), any substance</td>
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<tr>
<td>43257</td>
<td>Upper gastrointestinal endoscopy including esophagus, stomach, and either the duodenum and/or</td>
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<td></td>
<td>jejenum as appropriate; with delivery of thermal energy to the muscle of lower esophageal</td>
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<td>sphincter and/or gastric cardia, for treatment of gastroesophageal reflux disease</td>
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<td>43284</td>
<td>Laparoscopy, surgical, esophageal sphincter augmentation procedure, placement of sphincter</td>
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<td></td>
<td>augmentation device (ie, magnetic band), including cruroplasty when performed (Effective 01/01/17</td>
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<tr>
<td></td>
<td>new code)</td>
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<tr>
<td>43285</td>
<td>Removal of esophageal sphincter augmentation device (Effective 01/01/17 new code)</td>
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<tr>
<td>43289</td>
<td>Unlisted laparoscopy procedure, esophagus</td>
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<tr>
<td>43499</td>
<td>Unlisted procedure, esophagus</td>
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<tr>
<td>43659</td>
<td>Unlisted laparoscopy procedure, stomach</td>
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<tr>
<td>43999</td>
<td>Unlisted procedure, stomach</td>
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<tr>
<td>0392T</td>
<td>Laparoscopy, surgical, esophageal sphincter augmentation procedure, placement of sphincter</td>
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<tr>
<td></td>
<td>augmentation device (i.e., magnetic band) (Effective 12/31/16 deleted code)</td>
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REVISION HISTORY EXPLANATION

ORIGINAL EFFECTIVE DATE: 10/15/2008
08/15/09: Reviewed
03/18/13: Updated Advantage denial code
06/20/14: Changed title of policy from Stretta Endoscopic Radiofrequency Ablation System to Endoscopic Therapies for Gastroesophageal Reflux Disease (GERD). Added codes 43499 & 43999. Radiofrequency energy (Stretta® System) (43257) for GERD may be covered with a prior authorization for Advantage members. Policy reviewed by TAWG and updated to reflect most current clinical evidence.
08/22/14: Added codes 43201, 43236, 43289, 43659, C9724, C9737. Policy reviewed by TAWG and updated to reflect most current clinical evidence.
10/22/15: Added new effective 7/1/15 codes 0392T & 0393T as non-covered. Policy reviewed and updated to reflect most current clinical evidence per The Technology Assessment Working Group (TAWG).
10/28/16: C9724 & C9737 deleted effective 12/31/15 & 06/30/15. Added effective 1/1/16 new code 43210. Policy reviewed and updated to reflect most current clinical evidence per The Technology Assessment Working Group (TAWG).
03/24/17: Effective 12/31/16 deleted codes 0392T & 0393T that were non-covered for all product lines. Added effective 01/01/17 new codes 43284 & 43285 as covered with prior authorization for Advantage only per ODM guidelines. Policy reviewed and updated to reflect most current clinical evidence per The Technology Assessment Working Group (TAWG).
03/22/18: Transoral incisionless fundoplication (TIF) (e.g., EsophyX™) (43210) for GERD is now covered with prior authorization for Elite per CMS guidelines. Policy reviewed and updated to reflect most current clinical evidence per The Technology Assessment Working Group (TAWG).
12/15/2020: Medical policy placed on the new Paramount Medical Policy Format

REFERENCES/RESOURCES
Centers for Medicare and Medicaid Services, CMS Manual System and other CMS publications and services
Ohio Department of Medicaid
American Medical Association, Current Procedural Terminology (CPT®) and associated publications and services
Industry Standard Review
Hayes, Inc