Medical Coverage Policy | Transesophageal Endoscopic Treatments for Gastroesophageal Reflux Disease

EFFECTIVE DATE: 10|01|2015
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OVERVIEW

Transesophageal endoscopic therapies are being developed for the treatment of gastroesophageal reflux disease (GERD). A variety of procedures are being evaluated, including transesophageal (or transoral) incisionless fundoplication (TIF), application of radiofrequency (RF) energy, and injection/implantation of prosthetic devices or bulking agents.
Note: This policy does not pertain to treatment for Barrett's Esophagus, which is covered.

This policy is applicable to Commercial Products only. For Medicare Advantage Plans, see Related Policies section below.

MEDICAL CRITERIA

Not applicable

PRIOR AUTHORIZATION

Not applicable

POLICY STATEMENT

Commercial Products

The following procedures for the treatment gastroesophageal reflux disease are not medically necessary as the evidence is insufficient to determine the effects of the technology on health outcomes:

- Transoral incisionless fundoplication (TIF) (eg, EsophyX; MUSE)
- Transesophageal radiofrequency to create submucosal thermal lesions of the gastroesophageal junction (i.e., Stretta® procedure)
- Endoscopic submucosal implantation of a prosthesis or injection of a bulking agent (e.g., polymethylmethacrylate beads, zirconium oxide spheres)

Implantation of inert polymers (Enteryx™) is considered a **contract exclusion** as it was withdrawn from the market following serious complications.

COVERAGE

Benefits may vary between groups/contracts. Please refer to the appropriate Subscriber Agreement for the applicable services that are not medically necessary and contract exclusions.

BACKGROUND

Gastroesophageal Reflux Disease

Gastroesophageal reflux disease (GERD) is a common disorder characterized by heartburn and other symptoms related to reflux of stomach acid into the esophagus. Nearly all individuals experience such symptoms at some point in their lives; a smaller number have chronic symptoms and are at risk for complications of GERD. The prevalence of GERD has been estimated to be 10% to 20% in the Western world, with a lower prevalence in Asia.

Pathophysiology

The pathophysiology of GERD involves excessive exposure to stomach acid, which occurs for several reasons. There can be an incompetent barrier between the esophagus and stomach, either due to dysfunction

of the lower esophageal sphincter or incompetence of the diaphragm. Another mechanism is an abnormally slow clearance of stomach acid. In this situation, delayed clearance leads to an increased reservoir of stomach acid and a greater tendency to reflux.

In addition to troubling symptoms, some patients will have a more serious disease, which results in complications such a serosive esophagitis, dysphagia, Barrett esophagus, and esophageal carcinoma. Pulmonary complications may result from aspiration of stomach acid into the lungs and can include asthma, pulmonary fibrosis, and bronchitis, or symptoms of chronic hoarseness, cough, and sore throat.

Treatment
Guidelines on the management of GERD emphasize initial medical management. Weight loss, smoking cessation, head of the bed elevation, and elimination of food triggers are all recommended in recent practice guidelines.

Proton pump inhibitors (PPIs) have been shown to be the most effective medical treatment. In a Cochrane systematic review, van Pinxteren et al (2010) reported that PPIs demonstrated superiority to H 2-receptor antagonists and prokinetics in both network meta-analyses and direct comparisons.

Surgical Treatment
The most common surgical procedure used for GERD remains laparoscopic Nissen fundoplication; however, the utilization of this procedure steadily declined between 2009 and 2013 with the advancement of novel nonmedical (endoscopic and surgical) techniques.
Fundoplication involves wrapping a portion of the gastric fundus around the distal esophagus to increase lower esophageal sphincter pressure. If a hiatal hernia is present, the procedure also restores the position of the lower esophageal sphincter to the correct location. Laparoscopic fundoplication was introduced in 1991and has been rapidly adopted because it avoids complications associated with an open procedure. Although fundoplication results in a high proportion of patients reporting symptom relief, complications can occur, and sometimes require conversion to an open procedure. Patients who have relief of symptoms of GERD after fundoplication may have dysphagia or gas-bloat syndrome (excessive gastrointestinal gas).

Other Treatment Options
Due in part to the high prevalence of GERD, there has been interest in creating a minimally invasive transesophageal therapeutic alternative to open or laparoscopic fundoplication or chronic medical therapy. This type of procedure may be considered natural orifice transluminal surgery. Three types of procedures have been investigated.

1. Transesophageal endoscopic gastroplasty (gastroplication, transoral incisionless fundoplication) can be performed as an outpatient procedure. During this procedure, the fundus of the stomach is folded and then held in place with staples or fasteners that are deployed by the device. The endoscopic procedure is designed to recreate a valve and barrier to reflux.

2. Radiofrequency energy has been used to produce submucosal thermal lesions at the gastroesophageal junction (this technique has also been referred to as the Stretta procedure). Specifically, radiofrequency energy is applied through 4 electrodes inserted into the esophageal wall at multiple sites both above and below the squamocolumnar junction. The mechanism of action of the thermal lesions is not precisely known but may be related to the ablation of the nerve pathways responsible for sphincter relaxation or may induce a tissue-tightening effect related to heat-induced collagen contraction and fibrosis.

3. Submucosal injection or implantation of a prosthetic or bulking agent to enhance the volume of the lower esophageal sphincter has also been investigated. One bulking agent, pyrolytic carbon-coated zirconium oxidespheres (Durasphere), has been evaluated. The Gatekeeper™ Reflux Repair System

(Medtronic) used a soft, pliable, expandable prosthesis made of a polyacrylonitrile-based hydrogel. The prosthesis was implanted into the esophageal submucosa, and with time, the prosthesis absorbed water and expanded, creating bulk in the region of implantation. However, the only identified RCT was terminated early due to lack of efficacy, and it was voluntarily withdrawn by the manufacturer. Endoscopic submucosal implantation of polymethylmethacrylate beads into the lower esophageal folds has also been investigated.

Regulatory Status

The EsophyX® (EndoGastric Solutions) is a transesophageal (or transoral) incisionless fundoplication (TIF) device that was originally cleared for marketing by the FDA through the 510(k) process in 2007 and has subsequently undergone 2evolutions: Generation 2=EsophyX2 iterations (E2-Plus, HD) and Generation 3=Z iterations (EZ/ZR, Z+).

Some of the key Regulatory Status changes are summarized herein. In 2007, EsophyX® (EndoGastric Solutions) was cleared for marketing by the FDA through the 510(k) process for full-thickness plication. In 2016, EsophyX® Z Device with Serosa Fuse Fasteners was cleared for marketing by the FDA through the 510(k) process (K160960) for use in transoral tissue approximation, full-thickness plication, ligation in the gastrointestinal tract, narrowing the gastroesophageal junction, and reduction of hiatal hernias of 2 cm or less in patients with symptomatic chronic GERD.

In June 2017, EsophyX2 HD and the third generation EsophyX Z Devices with SerosaFuse fasteners and accessories were cleared for marketing by the FDA through the 510(k) process (K171307) for expanded indications, including patients who require and respond to pharmacologic therapy and patients with hiatal hernias larger than 2 cm when a laparoscopic hiatal hernia repair reduces a hernia to 2 cm or less.

The most recent FDA 510(k) clearance (K172811) occurred in October 2017for new product specification iterations of EsophyX2 HD and EsophyX Z Devices. This clearance allows for "a moderate increase in the upper limit of the temporary Tissue Mold clamping pressure occurring during each fastener deployment." FDA product code: ODE.

The Medigus SRS Endoscopic Stapling System (MUSE, Medigus) was cleared for marketing by the FDA through the510(k) process in 2012 (K120299) and 2014 (K132151). MUSE is intended for endoscopic placement of surgical staples in the soft tissue of the esophagus and stomach to create anterior partial fundoplication for the treatment of symptomatic chronic GERD in patients who require and respond to pharmacologic therapy. FDA product code: ODE.

In 2000, the CSM Stretta® System was cleared for marketing by the FDA through the 510(k) process for general use in the electrosurgical coagulation of tissue and was specifically intended for use in the treatment of GERD. In 2010, Mederi Therapeutics began manufacturing the Stretta® device. Mederi was acquired by Respiratory Technology Corporation in2018. FDA product code: GEI.

Durasphere® is a bulking agent approved for the treatment of urinary and fecal incontinence (see evidence review7.01.19). Use of this product for esophageal reflux would be considered off-label use. The website of Carbon Medical Technologies states that the Durasphere® GR product is “intended to treat problems associated with GERD” but is considered an investigational device in the U.S.

CODING

Commercial Products

The following CPT code(s) is not medically necessary:

43257 Upper gastrointestinal endoscopy, with delivery of thermal energy to the muscle of the lower esophageal sphincter and/or gastric cardia

The following CPT code(s) are not medically necessary when filed with ICD-10 Diagnosis K21.00-K21.9:

43201 Esophagoscopy, flexible, transoral; with directed submucosal injection(s), any substance
43210 Esophagogastroduodenoscopy, flexible, transoral; with esophagogastric fundoplasty, partial or complete, includes duodenoscopy when performed
43212 Esophagoscopy, flexible, transoral; with placement of endoscopic stent (includes pre- and post-dilation and guide wire passage, when performed)
43236 Esophagogastroduodenoscopy, flexible, transoral; with directed submucosal injection(s), any substance
43266 Esophagogastroduodenoscopy, flexible, transoral; with placement of endoscopic stent (includes pre- and dilation and guide wire passage, when performed)

RELATED POLICIES

Medicare Advantage Plans National and Local Coverage Determinations

PUBLISHED

Provider Update, December 2023
Provider Update, February/December 2022
Provider Update, February 2021
Provider Update, February 2020
Provider Update, February 2020

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