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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,

MEDICAL CRITERIA

None

PRIOR AUTHORIZATION

None

POLICY STATEMENT

BlueCHiP for Medicare

The implantation of an anti-gastroesophageal reflux device is considered medically necessary when used for the indications listed in the background.

Medicare policy is developed separately from BCBSRI policy. Medicare policy incorporates consideration of governmental regulations from the Centers for Medicare and Medicaid Services (CMS), such as national coverage determinations or local coverage determinations. In addition to benefit differences, CMS may reach different conclusions regarding the scientific evidence than does BCBSRI. Medicare and BCBSRI policies may differ. However, BlueCHiP for Medicare members must be offered, at least, the same services that Medicare offers.

Commercial Products

The following procedures for the treatment gastroesophageal reflux disease are not medically necessary as there is insufficient peer-reviewed scientific literature that demonstrates that the procedure/service is effective.

- Transoral incisionless fundoplication (TIF) (i.e., Esophyx®)
- 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Implantation of inert polymers (Enteryx™) is considered a **contract exclusion** as it was withdrawn from the market following serious complications.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 Evidence of Coverage or Subscriber Agreement for the applicable services that are not medically necessary and contract exclusions.

BACKGROUND

Due in part to the high prevalence of gastroesophageal reflux disease (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 (NOTES). Three types of procedures have been investigated:

1. Transesophageal endoscopic gastroplasty (gastroplication, fundoplication or transoral incisionless fundoplication [TIF]) is an outpatient procedure. During this procedure, suture(s) or fasteners are placed in the lower esophageal sphincter. The sutures/fasteners are designed to strengthen and lengthen the sphincter to decrease reflux.

Currently, 3 endoscopic suturing devices have received U.S. Food and Drug Administration (FDA) 510(k) marketing clearance for use in the treatment of GERD:

- EndoCinch™ (CR Bard, Murray Hill, NJ) is a suture technique for partial-thickness plication, approved January 2001
 - NDO Plicator™ (Ethicon Endo-Surgery, Chicago, IL) for full-thickness plication, approved May 2003
 - Esophyx (EndoGastric Solutions, Redmond, WA) for full-thickness plication, approved September 2007
2. Radiofrequency (RF) energy has been used to produce submucosal thermal lesions at the gastroesophageal junction. (This technique has also been referred to as the Stretta procedure. The CSM Stretta System [Conway Stuart] received 510(k) marketing clearance from the FDA in 2000 for general use in the electrosurgical coagulation of tissue and is specifically intended for use in the treatment of GERD. Stretta is currently manufactured by Mederi Therapeutics, Greenwich, CT.) Specifically, RF 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 ablation of the nerve pathways responsible for sphincter relaxation or may induce a tissue-tightening effect related to heat-induced collagen contraction.
 3. Submucosal injection or implantation of a prosthetic or bulking agent to enhance the volume of the lower esophageal sphincter has also been investigated.

In one procedure, a biocompatible liquid polymer is injected into the lower esophageal sphincter. On contact with the tissue, the polymer precipitates into a spongy mass. The mechanism of action in reducing reflux is not precisely known. One polymer, Enteryx, received FDA approval in 2003 through the premarket approval (PMA) process for the treatment of symptomatic GERD. However, on September 23, 2005, Boston Scientific Corporation issued a recall of Enteryx due to the device polymerizing shortly after injection into a spongy material that cannot be removed. Serious adverse events involved unrecognized transmural injections of Enteryx into structures surrounding the esophagus, potentially resulting in serious injury or death. In September 2005, Enteryx was voluntarily removed from the market due to serious adverse effects.

Another bulking agent, pyrolytic carbon-coated zirconium oxide spheres (Durasphere®), is being evaluated. Durasphere is a bulking agent approved for treatment of urinary and fecal incontinence (see policy number 7.01.19). Use of this product for esophageal reflux would be considered off-label use. The website of Carbon Medical Technologies states that Durasphere GR is an investigational device in the U.S. “intended to treat problems associated with GERD.”

The Gatekeeper Reflux Repair System (Medtronic, Shoreview, MN) 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.

Endoscopic submucosal implantation of polymethylmethacrylate beads into the lower esophageal folds has also been investigated.

There is insufficient evidence at present to establish the safety and efficacy of these procedures, particularly in the long term. Some of the unresolved issues include questions about the safety and durability of the device/treatment and lack of consistent improvement in objective measures (esophageal acid exposure) using these devices. A number of these devices (e.g., EndoCinch, NDO Plicator, Gatekeeper, Enteryx) are no longer marketed or actively evaluated due to lack of efficacy and/or safety issues. For procedures that are still in development, high-quality data from large randomized controlled trials are needed to compare endoscopic procedures with both sham controls and with the currently accepted treatments for GERD, namely drug therapy and laparoscopic fundoplication. Well-designed trials should use standardized outcome measures to examine whether subjective improvement, such as discontinuation of medication therapy and GERD-HRQL scores, is supported by objective improvement, such as esophageal acid exposure. Until such studies demonstrate improved net health outcomes for patients with GERD, these techniques are considered not medically necessary as there is no proven efficacy.

BlueCHiP for Medicare

The implantation of an anti-gastroesophageal reflux device is a surgical procedure for the treatment of gastroesophageal reflux, a condition in which the caustic contents of the stomach flow back into the esophagus. The procedure involves the implantation of this special device around the esophagus under the diaphragm and above the stomach, which is secured in place by a circumferential tie strap.

The implantation of this device may be considered reasonable and necessary in specific clinical situations where a conventional valvuloplasty procedure is contraindicated. The implantation of an anti-gastroesophageal reflux device is covered only for patients with documented severe or life threatening gastroesophageal reflux disease whose conditions have been resistant to medical treatment and who also:

- Have esophageal involvement with progressive systemic sclerosis; or
- Have foreshortening of the esophagus such that insufficient tissue exists to permit a valve reconstruction; or
- Are poor surgical risks for a valvuloplasty procedure; or
- Have failed previous attempts at surgical treatment with valvuloplasty procedures.

For all other indications, the implantation of an anti-gastroesophageal reflux device is considered not medically necessary due to no proven efficacy.

CODING

BlueCHiP for Medicare

The following CPT Code are medically necessary when used for a covered indication:

- 43201** Esophagoscopy, flexible, transoral; with directed submucosal injection(s), any substance
- 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
- 43257** Esophagogastroduodenoscopy, flexible, transoral; with delivery of thermal energy to the muscle of lower esophageal sphincter and/or gastric cardia, for treatment of gastroesophageal reflux disease
- 43266** Esophagogastroduodenoscopy, flexible, transoral; with placement of endoscopic stent (includes pre- and dilation and guide wire passage, when performed)

Commercial Products

The following CPT code 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 codes are not medically necessary when filed with ICD-10 diagnosis K21.9:

43201 Esophagoscopy, flexible, transoral; with directed submucosal injection(s), any substance

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

None

PUBLISHED

Provider Update August 2015

Provider Update, January 2014

Provider Update, January 2012

Provider Update, February 2011

Provider Update, September 2009

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