Protocol

Transesophageal Endoscopic Therapies for Gastroesophageal Reflux Disease

(20138)

Medical Benefit		**Effective Date**: 04/01/13	**Next Review Date**: 01/15
Preauthorization	No	**Review Dates**: 03/07, 05/08, 05/09, 03/10, 01/11, 01/12, 01/13, 01/14	

The following Protocol contains medical necessity criteria that apply for this service. It is applicable to Medicare Advantage products unless separate Medicare Advantage criteria are indicated. If the criteria are not met, reimbursement will be denied and the patient cannot be billed. ***Preauthorization is not required but is recommended if, despite this Protocol position, you feel this service is medically necessary; supporting documentation must be submitted to Utilization Management.*** *Please note that payment for covered services is subject to eligibility and the limitations noted in the patient's contract at the time the services are rendered.*

Description

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.

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, three endoscopic suturing devices have received U.S. Food and Drug Administration (FDA) 510(k) marketing clearance for use in the treatment of GERD:
   1. EndoCinch™ (CR Bard, Murray Hill, NJ) is a suture technique for partial-thickness plication, approved January 2001
   2. NDO Plicator™ (Ethicon Endo-Surgery, Chicago, IL) for full-thickness plication, approved May 2003
   3. 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 four 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.

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. 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.

Related Protocols

Endoscopic Radiofrequency Ablation or Cryoablation for Barrett's Esophagus

Injectable Bulking Agents for the Treatment of Urinary and Fecal Incontinence

Policy (Formerly Corporate Medical Guideline)

Transesophageal endoscopic gastroplasty is considered **investigational** as a treatment of gastroesophageal reflux disease (e.g., the EndoCinch™, NDO Plicator™, or Esophyx® procedures).

Transesophageal radiofrequency to create submucosal thermal lesions of the gastroesophageal junction (i.e., the Stretta procedure) is considered **investigational** as a treatment of gastroesophageal reflux disease.

Endoscopic submucosal implantation of a prosthesis or injection of a bulking agent (e.g., biocompatible liquid polymer, polymethylmethacrylate beads, zirconium oxide spheres) is considered **investigational** as a treatment of gastroesophageal reflux disease.

Services that are the subject of a clinical trial do not meet our Technology Assessment Protocol criteria and are considered investigational. *For explanation of experimental and investigational, please refer to the Technology Assessment Protocol.*

It is expected that only appropriate and medically necessary services will be rendered. We reserve the right to conduct prepayment and postpayment reviews to assess the medical appropriateness of the above-referenced procedures. **Some of this Protocol may not pertain to the patients you provide care to, as it may relate to products that are not available in your geographic area.**

References

We are not responsible for the continuing viability of web site addresses that may be listed in any references below.

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