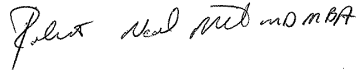


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Developed By: Medical Criteria Committee	



Approved: Robert Mills, MD

Date: 07/28/11

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:

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.

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.

Criteria:

ODS considers endoscopic procedures for the treatment and management of GERD to be experimental and investigational. 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 investigation include, but are not limited to the following:

- Angelchik anti-reflux prosthesis
- EndoCinch™ or Bard Endoscopic Suturing System (BESS)
- Enteryx
- EsophyX™ System or StomaphyX
- Full-Thickness Plicator™

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- Gatekeeper™ Reflux Repair System
- LINX Reflux Management System
- Plexiglas or polymethylmethacrylate implantation.
- Plicator System
- Stretta™ System
- Syntheon ARD Plicator

Information to be Submitted with Pre-Authorization Request:

None. Endoscopic procedures for the treatment and management of GERD are considered to be experimental/investigational by ODS.

Applicable CPT/HCPC Codes:

Note: list is not all inclusive

Codes	Description
43201	Esophagoscopy, rigid or flexible; with directed submucosal injection(s), any substance
43236	Upper gastrointestinal endoscopy including esophagus, stomach, and either the duodenum and/or jejunum as appropriate; with directed submucosal injection(s), any substance
43257	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
43499	Unlisted procedure, esophagus
C9724	Endoscopic full-thickness placcation in the gastric cardia using endoscopic placcation system (EPS); includes endoscopy

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