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Subject: Minimally Invasive Procedures for the Treatment of Gastroesophageal Reflux Disease (GERD) and Dysphagia

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DESCRIPTION:

Gastroesophageal reflux disease (GERD) is defined as the reflux of gastric contents into the esophagus, that causes symptoms and/or mucosal injury. Gastroesophageal reflux disease (GERD) is related to incompetence of the lower esophageal sphincter, and is a common medical disorder. Its severity varies widely. Many individuals have mild, intermittent symptoms that do not require treatment, or only require episodic use of medications. Others have chronic, severe GERD that can lead to complications such as Barrett's esophagus and esophageal cancer.

Endoscopic gastroplasty, also referred to as gastroplication, is a minimally invasive transesophageal therapeutic alternative to open or laparoscopic fundoplication or chronic medical therapy for the treatment of GERD. Endoscopic gastroplasty is an outpatient procedure that takes about 30 – 55 minutes and does not require general anesthesia. With endoscopic gastroplasty, sutures are placed in the lower esophageal sphincter. The sutures are designed to strengthen and lengthen the sphincter in order to decrease reflux. The Bard® EndoCinch™ is a device that has been approved by the U.S. Food and Drug Administration (FDA) for use in endoscopic suturing, and has been investigated as a device used in endoscopic gastroplasty.

Transoral incisionless fundoplication (TIF) is a minimally invasive procedure performed under general anesthesia using the EsophyX surgical device. The TIF procedure is referred to as a Natural Orifice Surgery (NOS) procedure because the EsophyX device is introduced into the body through the mouth, rather than through an abdominal incision, and is advanced into the esophagus under visualization of a video camera. Other devices used for this purpose include the Plicator and the StomaphyX.

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). 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 and fibrosis.

Enteryx™ is a liquid polymer that is endoscopically injected into the lower esophageal sphincter region for the treatment of GERD. On contact with the tissue, the polymer precipitates into a spongy mass. The mechanism of action in reducing reflux is not precisely known. Enteryx™ received FDA approval in 2003 through the PMA process for the treatment of symptomatic gastroesophageal reflux disease. 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 death or serious injury.

Polymethylmethacrylate (PMMA) microbead implantation involves the implantation of microscopic spheres of PMMA into the submucosa 1 or 2 cm proximal to the squamocolumnar junction. The purpose is to increase tissue thickness at the gastroesophageal junction, thereby narrowing the lower esophageal sphincter (LES) and reducing GERD. The process is performed under intravenous sedation.

A laparoscopically implanted ring composed of interlinked titanium beads with magnetic cores has been developed for the treatment of gastroesophageal reflux disease (GERD). The device is placed around the esophagus at the level of the gastroesophageal junction and is being evaluated in patients who have GERD symptoms despite maximum medical therapy. One such device is the LINX™ Reflux Management System, which is composed of a small flexible band of 10 to 18 interlinked titanium beads with magnetic cores. Using standard laparoscopic techniques, the band is placed around the esophagus at the level of the gastroesophageal junction. The magnetic attraction between the beads is intended to augment the lower esophageal sphincter to prevent gastric reflux into the esophagus, without compressing the esophageal wall.

Peroral endoscopic myotomy (POEM) is an endoscopic procedure that uses the oral cavity as a natural orifice entry point to perform myotomy of the lower esophageal sphincter (LES). This procedure is intended to reduce the total number of incisions needed and thus the overall invasiveness of surgery. POEM is performed under general anesthesia. After tunneling an endoscope down the esophagus toward the esophageal gastric junction, a surgeon performs the myotomy by cutting only the inner, circular lower esophageal sphincter (LES) muscles through a submucosal tunnel created in the proximal esophageal mucosa. POEM differs from laparoscopic surgery, which involves complete division of both circular and longitudinal LES muscle layers. Cutting the dysfunctional muscle fibers that prevent the LES from opening allows food to enter the stomach more easily.

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 oxide spheres (Durasphere), is being evaluated. The Gatekeeper Reflux Repair System uses 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.

POSITION STATEMENT:

1. Transesophageal endoscopic gastroplasty (i.e., the EndoCinch procedure or NDO Plicator procedure) is considered **experimental or investigational**, as there is insufficient clinical evidence to support the use of transesophageal endoscopic gastroplasty as a treatment of gastroesophageal reflux disease. Minimal data are available in peer-reviewed journals to permit conclusions about the effects of transesophageal endoscopic gastroplasty on GERD.
2. Transoral incisionless fundoplication (TIF) (i.e., Esophyx), for the treatment GERD is considered **experimental or investigational** as there is insufficient published long-term clinical evidence supporting the effects of this therapy on health outcomes.
3. Transesophageal radiofrequency to create submucosal thermal lesions of the gastroesophageal junction (i.e., the Stretta procedure) is considered **experimental or investigational**, as there is insufficient clinical evidence to support the use of transesophageal radiofrequency to create submucosal thermal lesions of the gastroesophageal junction as a treatment of gastroesophageal reflux disease. There are only a few case series and clinical trials, both having variable outcomes, to permit conclusions about the effects of transesophageal endoscopic gastroplasty on GERD. Additional comparative and longer-term efficacy and safety data are needed.
4. Endoscopic submucosal implantation of a biocompatible polymer (i.e., Enteryx) is considered **experimental or investigational**, as there is insufficient clinical evidence to support the use of endoscopic submucosal injection of a biocompatible polymer as a treatment of gastroesophageal reflux disease. There is inadequate data to determine whether or not injection of a polymer is at least as good as the established alternative of medical therapy.

NOTE: Endoscopic liquid polymer injection, Enteryx (Boston Scientific), was recalled 09/23/05 and is no longer available on the market.

5. Endoscopic submucosal implantation of a prosthesis or injection of a bulking agent (e.g., polymethylmethacrylate beads, zirconium oxide spheres) is considered **experimental or investigational**, as there is insufficient clinical evidence to support the use of endoscopic submucosal implantation of polymethylmethacrylate beads into the lower esophageal folds as a treatment of gastroesophageal reflux disease. There is insufficient peer-reviewed literature to permit conclusions about the effects of endoscopic submucosal implantation of polymethylmethacrylate beads on GERD.
6. Magnetic sphincter augmentation (e.g., LINX™ Reflux Management System) for the treatment of gastroesophageal reflux disease (GERD) is considered **experimental or investigational**. The clinical evidence published in the peer-reviewed literature is insufficient to permit conclusions concerning the effect of this procedure on net health outcomes.
7. Peroral endoscopic myotomy (POEM) is considered **experimental or investigational** as a treatment for dysphagia due to esophageal achalasia. There is insufficient published clinical evidence to determine safety and long-term efficacy.

BILLING/CODING INFORMATION:

CPT Coding:

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| 43210 | Esophagogastroduodenoscopy, flexible, transoral; with esophagogastric fundoplasty, partial or complete, includes duodenoscopy when performed (Investigational) |
| 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 [Stretta] (Investigational) |
| 43284 | Laparoscopy, surgical, esophageal sphincter augmentation procedure, placement of sphincter augmentation device (ie, magnetic band), including cruroplasty when |

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| | performed (Investigational) |
| 43285 | Removal of esophageal sphincter augmentation device (Investigational) |

REIMBURSEMENT INFORMATION:

Refer to section entitled [POSITION STATEMENT](#).

PROGRAM EXCEPTIONS:

Federal Employee Program (FEP): Follow FEP guidelines.

State Account Organization (SAO): Follow SAO guidelines.

Medicare Advantage products: The following National Coverage Determination (NCD) was reviewed on the last guideline reviewed date: Implantation of Anti-Gastroesophageal Reflux Device (100.9), located at cms.gov. The following Local Coverage Determinations (LCD) were reviewed on the last guideline reviewed date: Noncovered Procedures - Endoscopic Treatment of Gastroesophageal Reflux Disease (GERD) (L33296), and Noncovered Services (L33777), located at fcso.com.

DEFINITIONS:

Achalasia: a disorder of the esophagus characterized by reduced numbers of neurons in the esophageal myenteric plexuses and reduced peristaltic activity, making it difficult for patients to swallow food and possibly leading to complications such as regurgitation, coughing, choking, aspiration pneumonia, esophagitis, ulceration, and weight loss.

Dysphagia: Difficulty in swallowing.

Gastroesophageal junction: The lower part of the esophagus that connects to the stomach

Myotomy (i.e., Heller myotomy): a surgical procedure in which the muscles of the lower esophageal sphincter (LES) are cut, allowing food and liquids to pass to the stomach; used to treat achalasia.

Nissen fundoplication: A surgical procedure in which the upper portion of the stomach is wrapped around the lower end of the esophagus and sutured in place as a treatment for GERD.

Odynophagia: Pain produced by swallowing

Proton pump inhibitor (PPI): Any of a group of drugs (e.g., omeprazole) that inhibit the activity of proton pumps and are used to inhibit gastric acid secretion in the treatment of ulcers and gastroesophageal reflux disease.

RELATED GUIDELINES:

[Endoscopic Radiofrequency Ablation or Cryosurgical Ablation for Barrett's Esophagus, 01-9100-10](#)

OTHER:

NOTE: The use of specific product names is illustrative only. It is not intended to be a recommendation of one product over another, and is not intended to represent a complete listing of all products available.

Other names used to report minimally invasive procedures for treating gastroesophageal reflux disease:

- Bard Endoscopic Suturing System (BESS)
- Durasphere®
- EndoCinch™ Endoscopic Suturing System
- EndoLuminal gastroplication
- Endoscopic gastroplasty or gastroplication
- Endoscopic Plication™ System
- Enteryx device
- EsophyX™ System
- EsophyX™ System with SerosaFuse Fasteners
- Gastroesophageal Reflux Disease (GERD), Endoscopic Gastroplasty
- Gastroplasty or Gastroplication, Endoscopic
- Gatekeeper™ Reflux Repair System
- Implantable magnetic esophageal ring for GERD
- Laparoscopic implantation of magnetic esophageal ring
- LINX™ Reflux Management System
- Magnetic esophageal ring to GERD
- Magnetic sphincter augmentation (MSA)
- Mechanical sphincter augmentation (MSA)
- MUSE™ System
- NDO Plicator™ Procedure
- OverStitch Endoscopic Suturing System
- Plexiglas microspheres
- SRS™ Endoscopic Stapling System
- Stretta® System
- Syntheon ARD Plicator

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COMMITTEE APPROVAL:

This Medical Coverage Guideline (MCG) was approved by the Florida Blue Medical Policy & Coverage Committee on 01/24/19.

GUIDELINE UPDATE INFORMATION:

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| 06/15/01 | New Medical Coverage Guideline. |
| 03/15/02 | Additions to Non-Covered section/Added CPT code 0008T. |
| 04/15/03 | Medical Coverage Guideline Reviewed. |
| 01/01/04 | Annual HCPCS coding update. |
| 04/15/04 | Review and revision of guideline consisting of updated references and added information regarding endoscopic submucosal biocompatible polymer (investigational). |
| 10/01/04 | 4th quarter HCPCS coding update consisting of addition of S2215 (investigational). |
| 01/01/05 | Annual HCPCS update consisting of addition of 43257 and deletion of 0057T. |

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| 04/15/05 | Review and revision of guideline consisting of updated references. |
| 01/01/06 | Annual HCPCS coding update consisting of the deletion of S2215 and the addition of 0133T. |
| 04/15/06 | Review and revision of guideline consisting of updated references. |
| 01/01/07 | HCPCS update consisting of the deletion of 0008T. |
| 04/15/07 | Review and revision of guideline consisting of updated references. |
| 06/15/07 | Reformatted guideline. |
| 07/01/07 | HCPCS update consisting of the deletion of 0133T. |
| 03/15/08 | Review and revision of guideline consisting of updated references. |
| 03/15/09 | Review and revision of guideline consisting of updated references. |
| 05/15/09 | Scheduled review; added informational statements relating to Stretta and Enteryx; no change in position statements; references updated. |
| 06/15/10 | Scheduled review; position statement unchanged, references updated. |
| 03/15/11 | Review Position Statement for Stretta procedure; Position Statement unchanged. References updated. |
| 11/15/11 | Revision consisting of the addition of clarification regarding TIF and Esophyx. |
| 11/15/12 | Annual review; position statement unchanged; references updated. |
| 11/15/13 | Annual review; position statement unchanged; Coding section revised; Program Exceptions section updated; references updated. |
| 01/01/14 | Annual HCPCS coding update: added 43212 and 43266; revised 43201, 43236, and 43257. |
| 03/15/14 | Revision to add Position Statement regarding magnetic sphincter augmentation procedures; coding and references updated. |
| 10/15/14 | Annual review; add position statement for POEM; other position statements are unchanged; update Description and Definition sections; update references. |
| 07/01/15 | Quarterly CPT/HCPCS update: added codes 0392T and 0393T. |
| 06/15/16 | Unscheduled review. Revised description section, maintained position statement. Revised CPT coding, Medicare Advantage program exception, and index terms. Updated references. |
| 01/01/17 | Annual CPT/HCPCS update. Added 43284, 43285. Deleted 0392T, 0393T. |
| 02/15/17 | Scheduled review. Maintained Position Statement section. Revised Description section and index terms. Updated references. |
| 04/20/17 | Deleted code 43499. |
| 02/15/19 | Revision. Updated description section. Maintained position statement. Updated references. |
| 05/15/19 | Deleted codes 43201, 43212, 43236, 43241, and 43266. |