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

THIS MEDICAL COVERAGE GUIDELINE IS NOT AN AUTHORIZATION, CERTIFICATION, EXPLANATION OF BENEFITS, OR A GUARANTEE OF PAYMENT, NOR DOES IT SUBSTITUTE FOR OR CONSTITUTE MEDICAL ADVICE. ALL MEDICAL DECISIONS ARE SOLELY THE RESPONSIBILITY OF THE PATIENT AND PHYSICIAN. BENEFITS ARE DETERMINED BY THE GROUP CONTRACT, MEMBER BENEFIT BOOKLET, AND/OR INDIVIDUAL SUBSCRIBER CERTIFICATE IN EFFECT AT THE TIME SERVICES WERE RENDERED. THIS MEDICAL COVERAGE GUIDELINE APPLIES TO ALL LINES OF BUSINESS UNLESS OTHERWISE NOTED IN THE PROGRAM EXCEPTIONS SECTION.

Position Statement	Billing/Coding	Reimbursement	Program Exceptions	Definitions	Related Guidelines
Other	References	Updates			

DESCRIPTION:

Gastroesophageal reflux disease (GERD) is a common disorder characterized by heartburn and other symptoms related to reflux of stomach acid into the esophagus. 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. Treatment options for GERD include weight loss, smoking cessation, head of the bed elevation, elimination of food triggers, and proton pump inhibitors.

Esophageal achalasia is characterized by reduced numbers of neurons in the esophageal myenteric plexuses and reduced peristaltic activity, making it difficult to swallow food and possibly leading to complications such as regurgitation, coughing, choking, aspiration pneumonia, esophagitis, ulceration, and weight loss. Treatment options for esophageal achalasia include pharmacotherapy (eg, injections with botulinum toxin), pneumatic dilation, and laparoscopic Heller myotomy.

Surgical options investigated for treating GERD and dysphagia caused by achalasia include transesophageal endoscopic gastroplasty, transoral incisionless fundoplication (TIF), transesophageal radiofrequency to create submucosal thermal lesions of the gastroesophageal junction, endoscopic submucosal implantation of a biocompatible polymer, endoscopic submucosal implantation of a prosthesis or injection of a bulking agent, magnetic sphincter augmentation, and peroral endoscopic myotomy (POEM). Variations of peroral endoscopic myotomy (POEM) include diverticular peroral

endoscopic myotomy (D-POEM), gastric peroral endoscopic myotomy (G-POEM), and zenker peroral endoscopic myotomy (Z-POEM).

POSITION STATEMENT:

Peroral endoscopic myotomy (POEM) **meets the definition of medical necessity** when **ALL** of the following are met:

- Age 18 or older
- Primary idiopathic achalasia confirmed by esophageal manometry
- Eckardt symptom score (ESS)* is greater than 3
- No previous history of open surgery of the stomach or esophagus

The following procedures are considered **experimental or investigational**:

- Diverticular peroral endoscopic myotomy (D-POEM)
- Gastric peroral endoscopic myotomy (G-POEM)
- Zenker peroral endoscopic myotomy (Z-POEM)
- Transesophageal endoscopic gastroplasty
- Transoral incisionless fundoplication (TIF) (e.g., Esophyx)
- Transesophageal radiofrequency to create submucosal thermal lesions of the gastroesophageal junction (e.g., the Stretta procedure)
- Endoscopic submucosal implantation of a prosthesis or injection of a bulking agent (e.g., polymethylmethacrylate beads, zirconium oxide spheres)
- Magnetic sphincter augmentation (e.g., LINX™ Reflux Management System) for the treatment of GERD

There is a lack of clinical scientific evidence published in peer-reviewed literature to permit conclusions on safety and net health outcomes associated with the procedures listed above.

***Eckardt Symptom Score (ESS)**

Each symptom is graded on a score of 0 to 3, with a maximum score of 12.

Score	Recent weight loss (kg)	Dysphagia	Chest pain	Regurgitation
0	None	None	None	None
1	< 5kg	Occasional	Occasional	Occasional
2	5-10kg	Daily	Daily	Daily
3	> 10kg	Each meal	Several times per day	Each meal

BILLING/CODING INFORMATION:

CPT Coding:

43210	Esophagogastroduodenoscopy, flexible, transoral; with esophagogastric fundoplasty, partial or complete, includes duodenoscopy when performed (Investigational)
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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 performed (Investigational)
43285	Removal of esophageal sphincter augmentation device (Investigational)
43497	Lower esophageal myotomy, transoral (i.e., peroral endoscopic myotomy [POEM])

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: No National Coverage Determination (NCD) and/or Local Coverage Determination (LCD) were found at the time of the last guideline review date.

If this Medical Coverage Guideline contains a step therapy requirement, in compliance with Florida law 627.42393, members or providers may request a step therapy protocol exemption to this requirement if based on medical necessity. The process for requesting a protocol exemption can be found at [Coverage Protocol Exemption Request](#)

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 to swallow food and possibly leading to complications such as regurgitation, coughing, choking, aspiration pneumonia, esophagitis, ulceration, and weight loss.

Dysphagia: Difficulty in swallowing.

Eckardt symptom score: a grading system most frequently used for the evaluation of symptoms, stages and efficacy of achalasia treatment. It attributes points (0 to 3 points) for four symptoms of the disease (dysphagia, regurgitation, chest pain and weight loss), ranging from 0 to 12.

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, 01-91000-10](#)

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:

- Angelchik anti-reflux prosthesis
- ARD Plicator
- Bard Endoscopic Suturing System (BESS)
- Durasphere®
- EndoLuminal gastroplication
- Endoscopic gastroplasty or gastroplication
- Endoscopic Plicator™ System
- EsophyX™ System
- Gatekeeper™ Reflux Repair System
- Implantable magnetic esophageal ring
- LINX™ Reflux Management System
- Magnetic sphincter augmentation (MSA)
- Mechanical sphincter augmentation (MSA)
- MUSE™ System
- OverStitch Endoscopic Suturing System
- Plexiglas polymethylmethacrylate (PMMA) microspheres
- SRS™ Endoscopic Stapling System
- StomaphyX™ System
- Stretta® System

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COMMITTEE APPROVAL:

This Medical Coverage Guideline (MCG) was approved by the Florida Blue Medical Policy and Coverage Committee on 12/08/23.

GUIDELINE UPDATE INFORMATION:

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.
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.
12/15/19	Unscheduled review. Maintained position statement and updated references.
04/15/20	Unscheduled review. Maintained position statement and updated references.
11/15/20	Scheduled review. Revised description and maintained position statement. Updated references.
07/15/21	Revision. Updated references and Program Exceptions section, and maintained position statement.
09/15/22	Scheduled review. Revised description and CPT coding. Added coverage criteria for peroral endoscopic myotomy (POEM). Designated D-POEM, G-POEM, and Z-POEM as experimental or investigational. Revised definitions and updated references.
05/22/23	Update to Program Exceptions section.
08/15/23	Revision. Added Eckardt Symptom Score grid.
01/01/24	Position statements maintained.
02/15/24	Revision. Updated references and maintained position statements.