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| JOHNS HOPKINS HEALTH PLANS | Johns Hopkins Health Plans<br>**Medical Policy Manual**<br>**Medical Policy** | *Policy Number* | CMS20.03 |
| | | *Effective Date* | 08/01/2023 |
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| | *Subject*<br>**Gastroesophageal Reflux Disease (GERD) Devices** | *Supersedes Date* | 11/01/2022 |
| | | *Page* | 1 of 11 |

This document applies to the following Participating Organizations:

| | | | |
|---|---|---|---|
| EHP | Johns Hopkins Advantage MD | Johns Hopkins Health Plan of Virginia Inc. (JHHPVA) | Priority Partners |
| US Family Health Plan | | | |

**Keywords**: EsophyX, Gastroesophageal Reflux Disease, GERD, LINX, Stretta

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## I. ACTION

| | | |
|---|---|---|
| | New Policy | |
| x | Revising Policy Number | CMS20.03 |
| | Superseding Policy Number | |
| | Retiring Policy Number | |

## II. POLICY DISCLAIMER

Johns Hopkins Health Plans (JHHP) provides a full spectrum of health care products and services for Advantage MD, Employer Health Programs, Johns Hopkins Health Plan of Virginia Inc., Priority Partners, and US Family Health Plan. Each line of business possesses its own unique contract, benefits, regulations, and regulators' clinical guidelines that supersede the information outlined in this policy.

## III. POLICY

For Advantage MD refer to: Medicare Coverage Database

- National Coverage Determination (NCD) 100.2 Endoscopy
- Local Coverage Determination (LCD) L35350 Upper Gastrointestinal Endoscopy (Diagnostic and Therapeutic)

For Employer Health Programs (EHP) refer to:

- Plan specific Summary Plan Descriptions (SPDs)

For Johns Hopkins Health Plan of Virginia LLC (JHHPVA) refer to: Medicare Coverage Database (Effective 1/1/2024)

- National Coverage Determination (NCD) 100.2 Endoscopy
- Local Coverage Determination (LCD) L34434 Upper Gastrointestinal Endoscopy and Visualization

For Priority Partners (PPMCO) refer to: Code of Maryland Regulations

- No specific information located in COMAR 10.67.01-10.67.13 (Accessed 04/24/2023)

For US Family Health Plan (USFHP) refer to: Tricare Policy Manuals

- TRICARE Policy Manual 6010.63-M, April 1, 2021, Chapter 4, Section 13.1. Digestive System.

## IV. POLICY CRITERIA

A. General Considerations: When benefits are provided under the member's contract, JHHP considers anti-gastroesophageal reflux procedures medically necessary when procedure-specific and the following general considerations are met:
   1. Diagnosis of Gastrointestinal Reflux GERD by:
      a. Upper endoscopy showing reflux esophagitis; OR
      b. Twenty-four hour catheter-based pH impedance monitoring, OR minimum 48-hour Bravo capsule wireless pH monitoring confirms reflux; OR
      c. Biopsy-proven Barrett's esophagus
   2. Medical management with proton-pump inhibitor (PPI) documented showing:
      a. Response from maximum treatment with PPI's inadequate in controlling GERD symptoms; OR
      b. Contraindication to PPI's

B. Procedure Specific Criteria: When benefits are provided under the member's contract, JHHP considers the following anti-gastroesophageal reflux procedures medically necessary when the general considerations and procedure-specific criteria below are met:
   1. Magnetic Sphincter Augmentation (MSA) device (LINX® Reflux Management System)
      a. Member is age 21 or older, AND;
      b. Absence of the following contraindications to the LINX® procedure:
         i. Suspected or known allergies to titanium, stainless steel, nickel, or ferrous materials.
         ii. Implanted pacemaker or implantable cardioverter-defibrillator (ICD) or other metallic, abdominal implants
         iii. Barrett's esophagus or Grade C or D (LA classification) esophagitis (*Refer to Definitions*)
         iv. Unrepaired hiatal hernia greater than 3 cm.
         v. Scleroderma
         vi. Suspected or confirmed esophageal or gastric cancer
         vii. Prior esophageal or gastric surgery or endoscopic intervention
         viii. Distal esophageal motility less than 35 mmHg peristaltic amplitude on wet swallows or < 70% (propulsive) peristaltic sequences or High Resolution Manometry equivalent, and/or a known motility disorder such as Achalasia, Nutcracker Esophagus, and Diffuse Esophageal Spasm or Hypertensive lower esophageal sphincter (LES)
         ix. Symptoms of dysphagia more than once per week within the last 3 months
         x. Esophageal stricture or gross esophageal anatomic abnormalities (Schatzki's ring, obstructive lesions, etc.)
         xi. Esophageal or gastric varices

xii. Lactating, pregnant or plan to become pregnant
xiii. Morbid obesity (BMI >35)

*Note*: The LINX device is labeled MRI unsafe.

2. Transoral Incisionless Fundoplication (TIF) procedure (EsophyX®)
   a. Member is age 18 or older, AND;
   b. Anatomic disruption of the GE (Gastroesophageal) flap valve to a Hill Grade I-II (this is a mandatory requirement for TIF; cannot fix flaps that are Hill grade III or IV), AND;
   c. Absence of the following contraindications to the TIF procedure (EsophyX®):
      i. Bleeding disorder
      ii. Chronic uncontrollable cough
      iii. Severe Grade C or D esophagitis, or untreated dysplastic Barrett's esophagus (*Refer to Definitions*)
      iv. Esophageal diverticulae in the distal esophagus
      v. Paraesophageal hernia
      vi. Limited neck mobility (e.g., large osteophytes of the spine)
      vii. Esophageal varices
      viii. Active untreated esophageal infections
      ix. Esophageal stenosis/stricture/obstruction
      x. Morbid obesity (BMI > 35)
      xi. Abnormal esophageal anatomy or normal anatomy which would prohibit insertion of a device
      xii. Unrepaired hiatal hernia > 2cm in size

      *Note*: TIF procedure (EsophyX®) may be performed when a concurrent laparoscopic hernia repair reduces the hernia to 2 cm or less.

3. Radiofrequency Energy Application to the Lower Esophageal Sphincter (Stretta®)
   a. Member is age 18 or older, AND;
   b. Absence of the following contraindications to Stretta® procedure
      i. Achalasia or incomplete LES (lower esophageal sphincter) in response to swallow
      ii. Pregnancy
      iii. Poor surgical candidate, ASA IV classification
      iv. Hiatal hernia is > 2cm in size
      v. Member has an implant near the LES that could be conductive with RF energy
      vi. Dysphagia, or esophageal obstruction
      vii. Esophageal bleeding, or gas bloat
      viii. Barrett's metaplasia, deep ulcers, or active severe circumferential erosive esophagitis
      ix. Untreated or unstable hypertension, diabetes mellitus, heart disease, collagen vascular disease, steroid use, immunosuppressed state, or cardiac pacemaker
      x. Abnormal blood coagulation, or use of anticoagulant or platelet anti-aggregation therapy
      xi. Morbid obesity (BMI ≥ 35)

C. Exclusions: Unless specific benefits are provided under the member's contract, JHHP considers the following anti-gastroesophageal reflux procedures/devices experimental and investigational as they do not meet Technology Evaluation Criteria (TEC) (*list may not be all-inclusive*):
   1. EndoCinch™ Device
   2. StomaphyX™ Device
   3. NDO Plicator™
   4. Syntheon ARD Plicator
   5. Angelchick

6. Enteryx™
7. Durasphere®
8. Gatekeeper™ Reflux Repair System
9. Plexiglas polymethylmethacralate microspheres
10. GERDX™
11. Medigus Ultrasonic Surgical Endostapler (MUSE™)
12. RefluxStop™

## V. DEFINITIONS

Abnormal ph study: Gastroesophageal reflux during pH monitoring is a sudden decrease in intraesophageal pH to below 4.0, with the nadir pH being reached within 30 seconds from the beginning of the drop. Normal esophageal pH is considered to be close to pH 7.0. GERD patients are more likely to report heartburn at an intraesophageal pH below 4.0 (Tutuian, 2006).

American Society of Anesthesiologists (ASA) IV classification: A patient with severe systemic disease that is a constant threat to life. Adult examples, including but not limited to: Recent (< 3months) MI, CVA, TIA or CAD/stents, ongoing cardiac ischemia or severe valve dysfunction, severe reduction of ejection fraction, shock, sepsis, DIC, ARD, or ESRD not undergoing regularly scheduled dialysis (ASA, 2020).

Hill Classification: An endoscopic grading system for the gastroesophageal flap valve (GEFV) (Hansdotter, 2016).

| GRADE | DESCRIPTION |
|---|---|
| Grade I | A prominent fold of tissue along the lesser curvature next to the endoscope. |
| Grade II | The fold is less prominent and there are periods of opening and rapid closing around the endoscope. |
| Grade III | The fold is not prominent and the endoscope is not tightly gripped by the tissue. |
| Grade IV | There is no fold, and the lumen of the esophagus is open, often allowing the squamous epithelium to be viewed from below. A hiatal hernia is always present. |

Los Angeles Classification System:Grading system to describe the severity of esophagitis and used to guide management (Genta 2011, Sami, 2013, Kahrilas, 2022).

| GRADE | LESIONS |
|---|---|
| A | One (or more) mucosal break 5mm or less that does not extend between the tops of two mucosal folds |
| B | One (or more) mucosal break more than 5mm-long that does not extend between the tops of two mucosal folds |
| C | One (or more) mucosal break that is continuous between the tops of two or more mucosal folds but that involves less than 75% of the circumference |
| D | One (or more) mucosal break that involves at least 75% of the esophageal circumference |

Protein Pump Inhibitors (PPI): Medications that inhibit acid secretion, including esomeprazole (Nexium®), lansoprazole (Prevacid®), omeprazole (Prilosec®), pantoprazole (Protonix®), Rabeprazole (Aciphex®) (Vakil, 2021).

Technology Assessment: The systematic evaluation of the properties, effects and/or impacts of health technologies and interventions. It covers both the direct, intended consequences of technologies and interventions and their indirect, unintended consequences (World Health Organization, 2018).

Technology Evaluation Criteria (TEC): A service, device or supply must meet all of the following criteria:

1. The technology must have final approval from the appropriate government regulatory bodies for intended use
2. There must be sufficient evidence-based studies to permit conclusions concerning the effect of the technology on health outcomes
3. The technology must improve the member's net health outcome
4. The technology must be as beneficial as any established alternatives
5. The improvement must be attainable outside the investigational setting.

## VI. BACKGROUND

Gastroesophageal reflux disease (GERD) is a common condition occurring in 20% of adults in the United States and results from incompetence of the lower esophageal sphincter, which permits reflux of gastric contents into the esophagus, causing burning pain. Prolonged reflux may lead to esophagitis, esophageal ulcer, stricture, and rarely abnormal metaplasia of the esophageal epithelium (Barrett esophagus), a precursor to the development of adenocarcinoma of the esophagus (Lynch, 2022; Hayes, 2018; Schwaitzberg, 2022). There are several FDA-approved devices, described below, used in the treatment of gastroesophageal reflux disease.

The LINX Reflux Management System (Torax Medical, Inc./Ethicon, a subsidiary of Johnson & Johnson), is a flexible and expandable magnetic sphincter augmentation (MSA) device comprised of 10-18 magnetic beads that is placed laparoscopically around the external distal esophagus at the gastroesophageal junction to augment the lower esophageal sphincter (LES) preventing reflux (Hayes, 2018). The magnets have sufficient attraction to increase the LES closure pressure but permit food passage with swallowing (Schwaitzberg, 2022).

EsophyX (EndoGastric Solutions, Inc.) is a device used to perform Transoral Incisionless Fundoplication (TIF), a procedure intended to reconstruct the gastroesophageal valve (GEV) and restore the angle of His (the acute angle between the cardia and the esophagus) (ASGE, 2017). The procedure is performed by retracting the tissue at the squamocolumnar junction (Z-line), and attaching nonbiodegradable fasteners 1to 3 cm above the Z-line to plicate esophageal and gastric tissue. The procedure improves the anti-reflux barrier by reducing small hiatal hernias (less than or equal to 2 cm), if present, and by creating a valve of 2 to 3 cm in length with a >270° circumferential fundoplication. (ASGE, 2017; EndoGastric Solutions, 2022).

Stretta (Mederi Therapeutics, Inc., acquired by Restech) is an endoscopic device that delivers radiofrequency energy to the lower esophageal sphincter muscle and gastric cardia, which remodels the tissue to thicken the musculature and increases the size and amount of smooth muscle fibers for better barrier function (Hayes, 2017). Radiofrequency treatments in the treatment of GERD, "appear to reduce postprandial transient lower esophageal sphincter relaxations and decrease compliance of the gastroesophageal junction, may decrease esophageal acid sensitivity by inducing healing of esophageal erosive disease, and may improve gastroparesis" (Triadafilopoulos, 2022).

Many new endoluminal devices and therapies have been devised over the years to create a more effective antireflux barrier in patients with gastroesophageal reflux disease (GERD). Several of these therapies have been abandoned because they were ineffective and/or had significant adverse effects, such as the Gatekeeper, Enteryx, and Plexiglas microspheres (Hummel & Richards, 2015). The NDO Plicator device failed because of poor financial performance and the Syntheon ARD Plicator was never marketed for commercial use. The Durasphere, GERDX, and RefluxStop devices need larger completed randomized trials before implementing them in routine clinical practice (Mann, 2021; Prevost, 2021).

## VII. CODING DISCLAIMER



*Note:* The following CPT/HCPCS codes are included below for informational purposes and may not be all inclusive. Inclusion or exclusion of a CPT/HCPCS code(s) below does not signify or imply that the service described by the code is a covered or non-covered health service. Benefit coverage for health services is determined by the member's specific benefit plan document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee of payment. Other policies and coverage determination guidelines may apply.

*Note:* All inpatient admissions require preauthorization.

| ***Adherence to the provisions in this policy may be monitored and addressed through post payment data analysis and/or medical review audits*** |
|---|
| Advantage MD: Regulatory guidance supersedes JHHP Medical Policies. If there are no statutes, regulations, NCDs, LCDs, or LCAs, or other CMS guidelines, apply the Medical Policy criteria. |
| Employer Health Programs (EHP): Specific Summary Plan Descriptions (SPDs) supersedes JHHP Medical Policy. If there are no criteria in the SPD, apply the Medical Policy criteria. |
| Johns Hopkins Health Plan of Virginia, Inc. (JHHPVA): Regulatory guidance supersedes JHHP Medical Policies. If there are no statutes, regulations, NCDs, LCDs, or LCAs, or other CMS guidelines, apply the Medical Policy criteria. |
| Priority Partners (PPMCO): Regulatory guidance supersedes JHHP Medical Policy. If there are no criteria in COMAR regulations, or other State guidelines, apply the Medical Policy criteria. |
| US Family Health Plan (USFHP): Regulatory guidance supersedes JHHP Medical Policy. If there are no TRICARE policies, or other regulatory guidelines, apply the Medical Policy criteria. |

## VIII. CODING INFORMATION

| **CPT® CODES ARE FOR INFORMATIONAL PURPOSES** | |
|---|---|
| **CPT® CODES** | **DESCRIPTION** |
| 43210 | Esophagogastroduodenoscopy, flexible, transoral; with esophagogastric fundoplasty, partial or complete, includes duodenoscopy when performed |
| 43284 | Laparoscopy, surgical, esophageal sphincter augmentation procedure, placement of sphincter augmentation device (ie, magnetic band), including cruroplasty when performed |
| 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. |

## IX. REFERENCE STATEMENT

Analyses of the scientific and clinical references cited below were conducted and utilized by the Johns Hopkins Health Plan (JHHP) Medical Policy Team during the development and implementation of this medical policy. The Medical Policy Team will continue to monitor and review any newly published clinical evidence and revise the policy and adjust the references below accordingly if deemed necessary.

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## XI. APPROVALS

Historical Effective Dates: 10/22/2003, 10/22/2004, 10/21/2005, 05/30/2006, 10/13/2006, 03/03/2008, 03/02/2009, 06/04/2010, 08/23/2011, 03/07/2014, 06/06/2014, 12/04/2015, 06/02/2017, 03/02/2018, 08/02/2021, 11/01/2022, 08/01/2023