### Keywords
Gastroesophageal Reflux Disease, GERD

#### Table of Contents

<table>
<thead>
<tr>
<th>Section</th>
<th>Page Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>I. ACTION</td>
<td>1</td>
</tr>
<tr>
<td>II. POLICY DISCLAIMER</td>
<td>1</td>
</tr>
<tr>
<td>III. POLICY</td>
<td>1</td>
</tr>
<tr>
<td>IV. POLICY CRITERIA</td>
<td>2</td>
</tr>
<tr>
<td>A. ALL</td>
<td>2</td>
</tr>
<tr>
<td>V. DEFINITIONS</td>
<td>3</td>
</tr>
<tr>
<td>VI. BACKGROUND</td>
<td>4</td>
</tr>
<tr>
<td>VII. CODING DISCLAIMER</td>
<td>4</td>
</tr>
<tr>
<td>VIII. CODING INFORMATION</td>
<td>5</td>
</tr>
<tr>
<td>IX. REFERENCE STATEMENT</td>
<td>5</td>
</tr>
<tr>
<td>X. REFERENCE</td>
<td>6</td>
</tr>
<tr>
<td>XI. APPROVALS</td>
<td>8</td>
</tr>
</tbody>
</table>

### I. ACTION

<table>
<thead>
<tr>
<th>Action</th>
<th>Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>New Policy</td>
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<td>Superseding Policy Number</td>
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<tr>
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### II. POLICY DISCLAIMER

Johns Hopkins HealthCare LLC (JHHC) provides a full spectrum of health care products and services for Employer Health Programs, Priority Partners, Advantage MD and US Family Health Plan. Each line of business possesses its own unique contract and guidelines which, for benefit and payment purposes, should be consulted to know what benefits are available for reimbursement.

Specific contract benefits, guidelines or policies supersede the information outlined in this policy.

### III. POLICY

For US Family Health Plan, see TRICARE Policy Manual 6010.57-M, February 1, 2008, Digestive System, Chapter 4, Section 13.1.

For Advantage MD, see Medicare Coverage Database: Local Coverage Determination (LCD): Transoral Incisionless Fundoplication (L34999)

National Coverage Determination (NCD) for Implantation of Anti-Gastroesophageal Reflux Device (100.9)
IV. POLICY CRITERIA

A. When benefits are provided under the member’s contract, JHHC considers radiofrequency energy application to the lower esophageal sphincter (Stretta®) medically necessary for patients with gastroesophageal reflux disease refractory to medical therapy.

B. When benefits are provided under the member’s contract, JHHC considers magnetic sphincter augmentation (MSA) device (LINX Reflux Management System) implanted around the distal esophagus at the gastroesophageal junction, (magnetic forces attract the beads to each other holding the junction closed) medically necessary for patients with proton pump inhibitor (PPI)- refractory gastroesophageal reflux disease (GERD) who meet ALL of the following criteria:
1. Member should be 21 years of age or older, AND;
2. Typical GERD symptoms which include the following (list may not be all inclusive):
   1. Heartburn
   2. Pain or discomfort in the chest
   3. Excessive salivation
   4. Regurgitation
   5. Gas or bloating
   6. Difficulty swallowing
   7. Trouble sleeping
   8. Bad breath or sour taste in the mouth
   9. Sensitive to some foods & liquids, AND;
   3. Partial response to daily PPI therapy*, AND;
   4. Abnormal ph study**, AND;
   5. Absence of a large hiatal hernia (>3cm) or severe esophagitis, AND;
   6. Absence of esophageal or gastric cancer, AND;
   7. Absence of esophageal or gastric varices, AND;
   8. No prior esophageal or gastric surgery or endoscopic intervention, AND;
   9. No symptoms of dysphagia more than once per week within the last 3 months, AND;
   10. Member not currently lactating, pregnant or planning to become pregnant, AND;
   11. Absence of scleroderma, AND;
   12. Absence of esophageal stricture or gross esophageal anatomic abnormalities (Schatzki’s ring, obstructive lesions, etc.), AND;
   13. Absence of Morbid Obesity (BMI>35), AND;
   14. Absence of distal esophageal motility less than 35mmHg peristaltic amplitude on wet swallows <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 LES, AND;
   15. Absence of Barrett’s esophagus, AND;
   16. Member does not have any electrical implants such as defibrillators, pacemakers, or other metallic, abdominal implants.

C. When benefits are provided under the member's contract, JHHC considers Transoral Incisionless Fundoplication (TIF) procedure performed with the EsophyX® device to repair a defective gastroesophageal valve and to restore the gastroesophageal valve's function as a reflux barrier for the treatment of symptomatic chronic GERD medically necessary when ALL of the following criteria are met:
1. Member is >18 years of age, AND;
2. Member does not have hiatal hernia or hiatal hernia is≤ 2cm in size, AND;
3. Member has a body mass index (BMI) < 35, AND;
4. Absence of bleeding disorder, AND;
5. Anatomic disruption of the GE flap valve to a Hill Grade I-II (this is a mandatory requirement for TIF; cannot fix flaps that are Hill grade III and IV), AND;
6. Absence of stricture, AND;
7. Absence of severe esophagitis, AND;
8. Absence of esophageal diverticulae, AND;
9. Absence of obstruction, AND;
10. Absence of paraesophageal hernia, AND;
11. Absence of limited neck mobility, AND;
12. Absence of osteophytes of the spine, AND;
13. Absence of esophageal varices, AND;
14. Absence of esophageal infections or fungal disease, AND;
15. Ability to adhere to the postoperative diet recommended for appropriate healing, AND;
16. Absence of abnormal esophageal anatomy or normal anatomy which would prohibit insertion of device, AND;
17. Daily, bothersome GERD symptoms (> 1 year) despite PPI therapy (> 6 months), AND;
18. Clinical documentation to include the following:
   a. History and physical (H&P) documenting progress notes detailing patient's reflux disease, AND;
   b. PPI use for > 6 months, AND;
   c. EGD results detailing hiatal hernia size, if any and presence of esophagitis, AND;
19. Proven gastroesophageal reflux by either endoscopy, ambulatory pH off of PPI therapy, or barium swallow testing, OR;
20. Evidence of one of the following while on PPI therapy:
   a. Erosive esophagitis (erosions or ulceration during endoscopy), OR;
   b. Abnormal ambulatory pH study, OR;
   c. Biopsy confirmed changes characteristic of reflux esophagitis

D. Unless specific benefits are provided under the member’s contract, JHHC considers all other endoscopic anti-reflux devices, including but not limited to the following, experimental and investigational as they do not meet Technology Evaluation Criteria (TEC) #2-5. Refer to CMS01.00 Medical Policy Introduction Technology Evaluation Criteria (TEC) #2-5.

1. EndoCinch™ Devicebe
2. StomaphyX™ System
3. NDO Plicator™ and Syntheon ARD Plicator
4. Angelchik
5. Enteryx
6. DuraspHERE, Gatekeeper Reflux Repair System and Plexiglas polymethylmethacrylate microspheres

Note ~ Patients who have allergies to titanium, stainless steel, nickel or iron should NOT receive a LINX prosthesis. Patients who have the LINX device should not undergo magnetic resonance imaging (MRI).

V. DEFINITIONS

*PPI therapy is Proton pump inhibitor medications like Omeprazole®, (Esomeprazole) Nexium®, (Pantoprazole Sodium) Protonix®, ( Lansoprazole) Prevacid®, (Omeprazole) Prilosec®, and (Rabeprazole Sodium) Aciphex® and others are the main treatment. These medications reduce the amount of acid produced by the stomach. Lifelong treatment is required because medication only alters the pH of the refluxed contents and has no impact on the reflux mechanism (Hayes Inc., 2017).
**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 (Stefanidis, 2010).

VI. BACKGROUND

Gastroesophageal reflux disease (GERD) is a condition in which the stomach contents (food or liquid) reflux from the stomach back into the esophagus. GERD is common when the lower esophageal sphincter (LES) a ring of muscle that forms a valve at the lower end of the esophagus, where it joins the stomach) is weak and do not fully close to prevent food or other stomach juices from re-entering the esophagus. According to the Mayo Clinic, burning sensation in the chest (heartburn), chest pain, hoarseness/sore throat, and difficulty swallowing are all common symptoms of GERD. There are several devices used to improve symptoms in GERD patients. FDA-approved devices include the Bard EndoCinch Suturing System, Stretta System, and EsophyX System. These devices use non-invasive methods to reduce pain and discomfort in GERD patients.

The LINX Reflux Management System (Torax Medical, St. Paul, MN), is a flexible and expandable magnetic sphincter augmentation (MSA) device placed laparoscopically around the external gastroesophageal junction. The magnetic device augments the lower esophageal sphincter (LES) to prevent reflux into the esophagus but may also allow for normal LES opening during swallowing, belching, and vomiting that is not seen with fundoplication (Hayes Inc., 2017c).

EsophyX (EndoGastric Solutions, Inc.) uses Transoral Incisionless Fundoplication (TIF) to recreate a barrier to reflux, retracting the tissue at the Z line (the squamocolumnar junction, which normally corresponds to the GEJ) and attaching fasteners 1 cm above the Z line for a 270° valve of 2 to 3 cm in length. The TIF procedure with the EsophyX device reconstructs the antireflux valve at the entrance from the esophagus into the stomach. This valve opens and closes as you swallow food and acts as a physical barrier to reflux (Gerasimos, 2017).

VII. CODING DISCLAIMER

CPT Copyright 2018 American Medical Association. All rights reserved. CPT is a registered trademark of the American Medical Association.

Note: The following CPT/HCPCS codes are included below for informational purposes. Inclusion or exclusion of a CPT/HCPCS code(s) below does not signify or imply member coverage or provider reimbursement. The member’s specific benefit plan determines coverage and referral requirements. All inpatient admissions require preauthorization.

<table>
<thead>
<tr>
<th>Compliance with the provision in this policy may be monitored and addressed through post payment data analysis and/or medical review audits</th>
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<tr>
<td>Employer Health Programs (EHP) refer to specific Summary Plan Description (SPD). If there is no criteria in the SPD, apply the Medical Policy criteria.</td>
</tr>
<tr>
<td>Priority Partners (PPMCO) refer to COMAR guidelines and PPMCO SPD then apply the Medical Policy criteria.</td>
</tr>
<tr>
<td>US Family Health Plan (USFHP), TRICARE Medical Policy supersedes JHHC Medical Policy. If there is no Policy in TRICARE, apply the Medical Policy Criteria.</td>
</tr>
<tr>
<td>Advantage MD, LCD and NCD Medical Policy supersedes JHHC Medical Policy. If there is no LCD or NCD, apply the Medical Policy Criteria.</td>
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### VIII. CODING INFORMATION

#### PRE-AUTHORIZATION REQUIRED

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<thead>
<tr>
<th>CPT ® CODES</th>
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<tr>
<td>43210</td>
<td>Esophagogastroduodenoscopy, flexible, transoral; with esophagogastric fundoplasty, partial or complete, includes duodenoscopy when performed</td>
</tr>
<tr>
<td>43284</td>
<td>Laparoscopy, surgical, esophageal sphincter augmentation procedure, placement of sphincter augmentation device (ie, magnetic band), including cruroplasty when performed</td>
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#### NO PRE-AUTHORIZATION REQUIRED

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<tr>
<td>43257</td>
<td>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.</td>
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#### ICD10 AND REVENUE CODES ARE FOR INFORMATIONAL PURPOSES ONLY

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</tr>
</thead>
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<tr>
<td>K21.0</td>
<td>Gastro-esophageal reflux disease with esophagitis</td>
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<tr>
<td>K21.9</td>
<td>Gastro-esophageal reflux disease without esophagitis</td>
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</tbody>
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<tr>
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</tr>
</thead>
<tbody>
<tr>
<td>0360</td>
<td>Operating Room Services-General; Hospital; outpatient</td>
</tr>
<tr>
<td>0361</td>
<td>Operating Room Services-Minor Surgery: Hospital; outpatient</td>
</tr>
</tbody>
</table>

### IX. REFERENCE STATEMENT

Analyses of the scientific and clinical references cited below were conducted and utilized by the Johns Hopkins HealthCare LLC (JHHC) Medical Policy Team during the development and implementation of this medical policy. Per NCQA standards, the Medical Policy Team will continue to monitor and review any newly published clinical evidence and adjust the references below accordingly if deemed necessary.
X. REFERENCE


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XI. APPROVALS

Historic Effective Dates: 10/22/03, 10/22/04, 10/21/05, 05/30/06, 10/13/06, 03/03/08, 03/02/09, 06/04/10, 08/23/11, 03/07/14, 06/06/14, 12/04/2015, 06/02/17, 03/02/18