

## **Transesophageal Endoscopic Therapies for Gastroesophageal Reflux Disease (GERD)**

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### **IMPORTANT REMINDER**

*The Medicare Advantage Medical Policy manual is not intended to override the member Evidence of Coverage (EOC), which defines the insured's benefits, nor is it intended to dictate how providers are to practice medicine. Physicians and other health care providers are expected to exercise their medical judgment in providing the most appropriate care for the individual member.*

*The Medicare Advantage Medical Policies are designed to provide guidance regarding the decision-making process for the coverage or non-coverage of services or procedures in accordance with the member EOC and the Centers of Medicare and Medicaid Services (CMS) policies, when available. In the event of a conflict, applicable CMS policy or EOC language will take precedence over the Medicare Advantage Medical Policy. In the absence of CMS guidance for a requested service or procedure, the health plan may apply their Medical Policy Manual or MCG™ criteria, both of which are developed with an objective, evidence-based process using scientific evidence, current generally accepted standards of medical practice, and authoritative clinical practice guidelines.*

*Medicare and EOCs exclude from coverage, among other things, services or procedures considered to be investigational, cosmetic, or not medically necessary, and in some cases, providers may bill members for these non-covered services or procedures. Providers are encouraged to inform members in advance when they may be financially responsible for the cost of non-covered or excluded services.*

## **DESCRIPTION**

Gastroesophageal reflux disease, or GERD, is a condition characterized by heartburn and other symptoms related to reflux of stomach acid into the esophagus. Non-surgical treatments include lifestyle modifications, which may vary for the individual patient (i.e., dietary changes, smoking cessation, avoidance of foods that may trigger reflux symptoms, sitting upright following a meal, etc.) or pharmacologic acid therapies such as antacids or proton pump inhibitors (PPIs). However, for some patients, these treatments may not be effective or tolerated, at which time, other anti-reflux options may be considered. Among them, transesophageal endoscopic therapies are minimally invasive antireflux procedures being investigated as alternatives to medical management or fundoplication surgery in the treatment of GERD.

## MEDICARE ADVANTAGE POLICY CRITERIA

| Procedure(s):                                                                                                                                                      | CPT and/or HCPCS codes     | CMS Coverage Manuals, National Coverage Determinations (NCD), Noridian Local Coverage Determinations (LCD) and Articles (LCA) | Medical Policy Manual                                                                                                                                                                                                                                                                                                                                                                                                                          |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|-------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Transesophageal radiofrequency energy                                                                                                                              | 43257                      | Non-Covered Services<br>( <a href="#">L35008</a> )                                                                            |                                                                                                                                                                                                                                                                                                                                                                                                                                                |
| <b>Examples:</b>                                                                                                                                                   |                            |                                                                                                                               |                                                                                                                                                                                                                                                                                                                                                                                                                                                |
| <ul style="list-style-type: none"> <li>CSM Stretta™ System, or the Stretta procedure</li> </ul>                                                                    |                            |                                                                                                                               |                                                                                                                                                                                                                                                                                                                                                                                                                                                |
| Endoscopic injection of a bulking agent                                                                                                                            | 43192, 43201, 43236, 43499 | None                                                                                                                          | <i>Medicare coverage guidance is not available in the health plan's service area for endoscopic injections of bulking agents, endoscopic submucosal implantation, or injection of a biocompatible polymer for GERD. Medicare coverage guidance is also not available in the health plan's service area for transesophageal endoscopic gastroplasty for GERD. Therefore, the health plan's medical policy is applicable for these services.</i> |
| <b>Examples:</b>                                                                                                                                                   |                            |                                                                                                                               |                                                                                                                                                                                                                                                                                                                                                                                                                                                |
| <ul style="list-style-type: none"> <li>pyrolytic carbon-coated zirconium oxide spheres (Durasphere®)</li> </ul>                                                    |                            |                                                                                                                               |                                                                                                                                                                                                                                                                                                                                                                                                                                                |
| Endoscopic submucosal implantation or injection of a biocompatible polymer                                                                                         |                            |                                                                                                                               | Transesophageal Endoscopic Therapies for Gastroesophageal Reflux Disease (GERD), Surgery, <a href="#">Policy No. 110</a> (see "Note" below)                                                                                                                                                                                                                                                                                                    |
| <b>Examples:</b>                                                                                                                                                   |                            |                                                                                                                               |                                                                                                                                                                                                                                                                                                                                                                                                                                                |
| <ul style="list-style-type: none"> <li>Enteryx,</li> <li>polymethylmethacrylate [PMMA] beads<sup>(1)</sup></li> <li>the Gatekeeper Reflux Repair system</li> </ul> |                            |                                                                                                                               |                                                                                                                                                                                                                                                                                                                                                                                                                                                |

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## Transesophageal endoscopic gastroplasty

### **Examples:**

- MUSE
- EndoCinch
- Plicator
- StomaphyX
- **Note:** *This does **not** include transoral incisionless fundoplication, or TIF (i.e., EsophyX; CPT 43210), which may be considered medically necessary for Medicare Advantage,*

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**NOTE:** If a procedure or device lacks scientific evidence regarding safety and efficacy because it is investigational or experimental, the service is noncovered as not reasonable and necessary to treat illness or injury. ([Medicare IOM Pub. No. 100-04, Ch. 23, §30 A](#)). According to Title XVIII of the Social Security Act, §1862(a)(1)(A), only medically reasonable and necessary services are covered by Medicare. In the absence of a NCD, LCD, or other coverage guideline, CMS guidelines allow a Medicare Advantage Organization (MAO) to make coverage determinations, applying an **objective, evidence-based process, based on authoritative evidence**. ([Medicare IOM Pub. No. 100-16, Ch. 4, §90.5](#)). The Medicare Advantage Medical Policy - Medicine Policy No. M-149 - provides further details regarding the plan's evidence-assessment process (see Cross References).

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## POLICY GUIDELINES

### REGULATORY STATUS

| DEVICE NAME                                       | MANUFACTURER                          | FDA APPROVAL                                                                   |
|---------------------------------------------------|---------------------------------------|--------------------------------------------------------------------------------|
| EsophyX®                                          | EndoGastric Solutions, Redmond,<br>WA | 2007                                                                           |
| EsophyX® Z                                        |                                       | 2016                                                                           |
| EsophyX2 HD and the<br>third-generation EsophyX Z |                                       | 2017                                                                           |
| Medigus SRS Endoscopic<br>Stapling System         | MUSE, Medigus                         | 2012 and 2014                                                                  |
| CSM Stretta® System                               | Mederi Therapeutics                   | 2000                                                                           |
| Durasphere®                                       | Carbon Medical Technologies           | 1999<br><i>(Use of this product for<br/>GERD would be “off-label”<br/>use)</i> |

Note the fact a service or procedure has been “FDA approved for a specific indication does not, in itself, make the procedure medically reasonable and necessary.” Medicare contractors evaluate services, procedures, drugs or technology to determine if they may be considered Medicare covered services. (*Noridian LCD L35008*) The FDA determines safety and effectiveness of a device or drug, but does not establish medical necessity. While Medicare may adopt FDA determinations regarding safety and effectiveness, CMS or Medicare contractors evaluate whether or not the drug or device is reasonable and necessary for the Medicare population under §1862(a)(1)(A).

## CROSS REFERENCES

[Investigational \(Experimental\) Services and New and Emerging Medical Technologies and Procedures](#), Medicine, Policy No. M-149

[Gastroesophageal Reflux Surgery](#), Surgery, Policy No. M-186

[Magnetic Esophageal Ring to Treat Gastroesophageal Reflux Disease \(GERD\)](#), Surgery, Policy No. M-190

## REFERENCES

1. FDA Website for [Soft Tissue Fillers \(Dermal Fillers\)](#)
2. NCD for Endoscopy ([100.2](#))

## CODING

| Codes | Number | Description                                                                                                                                          |
|-------|--------|------------------------------------------------------------------------------------------------------------------------------------------------------|
| CPT   | 43192  | Esophagoscopy, rigid, transoral; with directed submucosal injection(s), any substance                                                                |
|       | 43201  | Esophagoscopy; rigid or flexible; with directed submucosal injection(s), any substance                                                               |
|       | 43210  | Esophagogastroduodenoscopy, flexible, transoral; with esophagogastric fundoplasty, partial or complete, includes duodenoscopy when performed         |
|       | 43236  | Esophagogastroduodenoscopy, flexible, transoral, with direct submucosal injections, any substance                                                    |
|       | 43257  | ; with delivery of thermal energy to the muscle of lower esophagus sphincter and/or gastric cardia, for treatment of gastroesophageal reflux disease |
|       | 43499  | Unlisted procedure, esophagus                                                                                                                        |
| HCPCS | None   |                                                                                                                                                      |

**\*IMPORTANT NOTE:** Medicare Advantage medical policies use the most current Medicare references available at the time the policy was developed. Links to Medicare references will take viewers to external websites outside of the health plan's web control as these sites are not maintained by the health plan.