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Medicare Advantage Policy Manual

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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

Note: Transoral incisionless fundoplication, or TIF (i.e., EsophyX; CPT 43210) may be considered medically necessary for Medicare Advantage.

CMS Coverage Manuals* None

National Coverage Determinations (NCDs)* None

Noridian Healthcare Solutions (Noridian) Local Coverage Determinations (LCDs) and Articles (Articles)* None

Medical Policy Manual *Medicare coverage guidance is not available for transesophageal endoscopic therapies for gastroesophageal reflux disease (GERD). Therefore, the health plan's medical policy is applicable.*

Transesophageal Endoscopic Therapies for Gastroesophageal Reflux Disease (GERD), Surgery, [Policy No. 110](#) (see "Note" below)

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).

POLICY GUIDELINES

REGULATORY STATUS

DEVICE NAME	MANUFACTURER	FDA APPROVAL
EsophyX®	EndoGastric Solutions, Redmond, WA	2007
EsophyX® Z		2016
EsophyX2 HD and the third-generation EsophyX Z		2017
Medigus SRS Endoscopic Stapling System	MUSE, Medigus	2012 and 2014
GERDX-System	G-Surg GmbH	2024
CSM Stretta® System	Mederi Therapeutics	2000

DEVICE NAME	MANUFACTURER	FDA APPROVAL
Durasphere®	Carbon Medical Technologies	1999 <i>(Use of this product for GERD would be “off-label” use)</i>

Note the fact a service or procedure has been issued a CPT/HCPCS code or has been FDA approved for a specific indication does not, in itself, make the procedure medically reasonable and necessary. The FDA determines safety and effectiveness of a device or drug but does not establish medical necessity. While FDA determinations regarding safety and effectiveness may be considered, Medicare 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, New and Emerging Medical Technologies and Procedures, and Other Non-Covered Services](#), 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 [Dermal Fillers \(Soft Tissue Fillers\) | FDA](#)
2. NCD for Endoscopy (100.2) *(This reference can be found on the [Medicare Coverage Database](#) website)*

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.