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Medicare Advantage Policy Manual

Policy ID: M-SUR190

## **Magnetic Esophageal Ring to Treat Gastroesophageal Reflux Disease (GERD)**

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**Medicare Link(s) Revised:** N/A

### **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**

The LINX™ Reflux Management System consists of a series of titanium beads, each with a magnetic core, connected together with titanium wires to form a ring shape. The LINX device is placed around the lower end of the esophagus and is being evaluated as a treatment of gastroesophageal reflux disease (GERD) in patients who continue to have GERD symptoms despite the use of maximum medical therapy for the treatment of their reflux.<sup>[1]</sup>

## **MEDICARE ADVANTAGE POLICY CRITERIA**

### **CMS Coverage Manuals\***

According to the [Medicare Benefit Policy Manual](#) (sec. 180) regarding excluded services:

After a beneficiary has been discharged from the hospital stay in which the beneficiary received non-covered services, medical and hospital services

required to treat a condition or complication that arises as a result of the prior non-covered services may be covered when they are reasonable and necessary in all other respects. Thus, coverage could be provided for subsequent inpatient stays or outpatient treatment ordinarily covered by Medicare, even if the need for treatment arose because of a previous non-covered procedure.

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<b>National Coverage Determinations (NCDs)*</b>	None
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<b>Noridian Healthcare Solutions (Noridian) Local Coverage Determinations (LCDs) and Articles*</b>	None
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<b>Medical Policy Manual</b>	<i>Medicare coverage guidance is not available for the use of magnetic esophageal rings to treat GERD. Therefore, the health plan's medical policy is applicable.</i>
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Magnetic Esophageal Ring to Treat Gastroesophageal Reflux Disease (GERD), Surgery, [Policy No. 190](#) (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

The LINX™ Reflux Management System was approved by the U.S. Food and Drug Administration (FDA) in 2012, and is indicated for patients diagnosed with GERD, as defined by abnormal pH testing, and who continue to have chronic GERD symptoms despite maximum therapy for the treatment of reflux. The FDA has required 5-year follow-up of 100 patients from the investigational device exemption (IDE) pivotal study to evaluate safety and efficacy of the device. <sup>[1]</sup> Note, the fact a service or procedure has been issued a CPT/HCPCS code or is 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 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, New and Emerging Medical Technologies and Procedures, and Other Non-Covered Services](#), Medicine, Policy No. M-149

[Transesophageal Endoscopic Therapies for Gastroesophageal Reflux Disease \(GERD\)](#), Surgery, Policy No. M-110

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

## REFERENCES

1. FDA website, LINX™ Reflux Management System - P100049. [cited 03/6/2023] Available from: [https://www.accessdata.fda.gov/cdrh\\_docs/pdf10/P100049A.pdf](https://www.accessdata.fda.gov/cdrh_docs/pdf10/P100049A.pdf)

## CODING

Codes	Number	Description
<b>CPT</b>	43284	Laparoscopy, surgical, esophageal sphincter augmentation procedure, placement of sphincter augmentation device (ie, magnetic band), including cruroplasty when performed
	43285	Removal of esophageal sphincter augmentation device
	43289	Unlisted laparoscopy procedure, esophagus
<b>HCPCS</b>	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.