# *Medicare Medical Policy*

# Magnetic Esophageal Ring for Gastroesophageal Reflux Disease (GERD)

**MEDICARE MEDICAL POLICY NUMBER:** 394

**Effective Date:** 8/1/2024

**Last Review Date:** 6/2024

**Next Annual Review:** 6/2025



**INSTRUCTIONS FOR USE:** Company Medicare Medical Policies serve as guidance for the administration of plan benefits and do not constitute medical advice nor a guarantee of coverage. Company Medicare Medical Policies are reviewed annually to guide the coverage or non-coverage decision-making process for services or procedures in accordance with member benefit contracts (otherwise known as Evidence of Coverage or EOCs) and Centers of Medicare and Medicaid Services (CMS) policies, manuals, and other CMS rules and regulations. In the absence of a CMS coverage determination or specific regulation for a requested service, item or procedure, Company policy criteria or applicable utilization management vendor criteria may be applied. These are based upon published, peer-reviewed scientific evidence and evidence-based clinical practice guidelines that are available as of the last policy update. Coverage decisions are made on the basis of individualized determinations of medical necessity and the experimental or investigational character of the treatment in the individual case. In cases where medical necessity is not established by policy for specific treatment modalities, evidence not previously considered regarding the efficacy of the modality that is presented shall be given consideration to determine if the policy represents current standards of care.

The Company reserves the right to determine the application of Medicare Medical Policies and make revisions to these policies at any time. Any conflict or variance between the EOC and Company Medical Policy will be resolved in favor of the EOC.

**SCOPE:** Providence Health Plan, Providence Health Assurance, and Providence Plan Partners as applicable (referred to individually as “Company” and collectively as “Companies”).

## *PRODUCT AND BENEFIT APPLICATION*

☒ Medicare Only

## MEDICARE COVERAGE CRITERIA

**IMPORTANT NOTE:** More than one Centers for Medicare and Medicaid Services (CMS) reference may apply to the same health care service, such as when more than one coverage policy is available (e.g., both an NCD and LCD exist). All references listed should be considered for coverage decision-making. The Company uses the most current version of a Medicare reference available at the time of publication; however, these websites are not maintained by the Company, so Medicare references and their corresponding hyperlinks may change at any time. If there is a conflict between the Company Medicare Medical Policy and CMS guidance, the CMS guidance will govern.

| Service | Medicare Guidelines |
|---|---|
| *Removal of Implantable Magnetic Esophageal Ring for GERD (CPT 43285)* ***without*** *a Replacement Device* | Medicare Benefit Policy Manual, Chapter 16 - General Exclusions From Coverage, §180 - Services Related to and Required as a Result of Services Which Are Not Covered Under Medicare<br><br>**NOTE:** According to the above Medicare manual, removal **without** replacement (43285) may be considered medically reasonable and necessary for unrelated reasons (e.g., difficulty swallowing, pain, infection, erosion, device migration, etc.). |
| **Medicare Coverage Criteria:** "MA organizations may create publicly accessible internal coverage criteria… when coverage criteria are not fully established in applicable Medicare statutes, regulations, NCDs or LCDs." *(§ 422.101(b)(6) – see Policy Guidelines below)*<br>• **Medicare Coverage Manuals:** Medicare does not have criteria for the use of an implantable magnetic esophageal ring in the treatment of GERD (e.g., the LINX® Reflux Management System) in a coverage manual.<br>• **National Coverage Determination (NCD):** Medicare does not have an NCD for the use of implantable magnetic esophageal ring for the treatment of GERD.<br>• **Noridian J-F Local Coverage Determination (LCD)/Local Coverage Article (LCA):** As of the most recent policy review, one Medicare Administrative Contractor (MAC) has an LCD for the use of an implantable magnetic esophageal ring in the treatment of GERD. However, this MAC does not have jurisdiction over the plan service area and therefore, does not apply.<br>• Therefore, in the absence of established Medicare coverage criteria in a manual, NCD, LCD, or other regulatory guidance for the health plan's service area, Company criteria below are applied for medical necessity decision-making. | |
| *Insertion of Implantable Magnetic Esophageal Ring (e.g., LINX® Reflux Management System) (CPT* | Company medical policy for Gastroesophageal Reflux: Magnetic Esophageal Ring |

| | | |
|---|---|---|
| *43284) and Removal **with** a Replacement Device* | I. | This service is considered **not medically necessary** for Medicare based on the Company medical policy. *See Policy Guidelines below.* |

**IMPORTANT NOTICE:** While some services or items may appear medically indicated for an individual, they may also be a direct exclusion of Medicare or the member's benefit plan. Such excluded services or items by Medicare and member EOCs include, but are not limited to, services or procedures considered to be cosmetic, not medical in nature, or those considered not medically reasonable or necessary under *Title XVIII of the Social Security Act, §1862(a)(1)(A).* If there is uncertainty regarding coverage of a service or item, please review the member EOC or submit a pre-service organization determination request. Note that the Medicare Advance Beneficiary Notice of Noncoverage (ABN) form **cannot** be used for Medicare Advantage members. *(Medicare Advance Written Notices of Non-coverage. MLN006266 May 2021)*

## POLICY CROSS REFERENCES

None

**The full Company portfolio of Medicare Medical Policies is available online and can be accessed here.**

## POLICY GUIDELINES

**BACKGROUND**

The LINX® Reflux Management System is intended to treat chronic gastroesophageal reflux disease (GERD).

**MEDICARE AND MEDICAL NECESSITY**

Only medically reasonable and necessary services or items which treat illness or injury are eligible for Medicare coverage, as outlined in *Title XVIII of the Social Security Act, §1862(a)(1)(A)*. MA organizations (MAOs) make medical necessity determinations based on coverage and benefit criteria, current standards of care, the member's unique personal medical history (e.g., diagnoses, conditions, functional status, co-morbidities, etc.), physician recommendations, and clinical notes, as well as involvement of a plan medical director, where appropriate. *(§ 422.101(c)(1))*

In addition:

> "MA organizations may create publicly accessible internal coverage criteria that are based on current evidence in widely used treatment guidelines or clinical literature when coverage criteria are not fully established in applicable Medicare statutes, regulations, NCDs or LCDs. Current, widely-used treatment guidelines are those developed by organizations representing clinical medical specialties, and refers to guidelines for the treatment of specific diseases or conditions. Acceptable clinical literature includes large, randomized controlled trials or prospective cohort studies with clear results, published in a peer-reviewed journal, and specifically designed to answer the relevant clinical question, or large systematic reviews or meta-analyses summarizing the literature of the specific clinical question." *(§ 422.101(b)(6) and Medicare Managed Care Manual, Ch. 4, §90.5)*

The Company policy for *PHA Medicare Medical Policy Development and Application* (MP50) provides details regarding Medicare's definition of medical necessity and the hierarchy of Medicare references and resources during the development of medical policies, as well as the Plan's use of evidence-based processes for policy development.

Prior to 1/1/2021, the national coverage determination (NCD) for *Implantation of Anti-Gastroesophageal Reflux Device* was available (100.9). However, it was based on a different medical technology.

> "The 1987 Noncoverage NCD was determined based on a different device, the Angelchik device, which was a device implanted around the esophagus (under the diaphragm and above the stomach) that was secured by a circumferential tie strap. Implantable treatment for GERD initiated with Angelchik prosthetic rings came under scrutiny for high dysphagia rates and migration of the implant. It was removed from the market in 1990."[1]

On April 10, 2023, CMS retired this NCD, with retroactive effective date of January 1, 2021.

Only one Medicare Contractor (MAC) has a local coverage determination (LCD) or article (LCA) which addresses the LINX procedure (National Government Services LCD L35080 and LCA A56863), but it is not the MAC for the health plan and therefore would not have jurisdiction over the health plan's service area. However, this MAC considers this medical technology to be non-covered (not medically necessary).

The MAC for the health plan service area – Noridian – ***used to*** have an LCA for *Billing and Coding: Non-Covered Services* (A57642), which was retired in July 2020, but which considered CPT codes 43284 and 43285 to be non-covered.

Since there are not fully established Medicare coverage criteria for the use of an implantable magnetic esophageal ring in the treatment of GERD (e.g., LINX Reflux Management System) available in applicable Medicare statutes, regulations, NCDs or LCDs, then Company medical policy criteria for LINX Reflux Management System will be applied. The Company medical policy non-coverage position is consistent with the above noted Medicare references.

## *REGULATORY STATUS*

**U.S. FOOD & DRUG ADMINISTRATION (FDA)**

While clearance by the Food and Drug Administration (FDA) is a prerequisite for Medicare coverage, the 510(k) premarket clearance process does not in itself establish medical necessity. Medicare payment policy is determined by the interaction of numerous requirements, including but not limited to, the availability of a Medicare benefit category and other statutory requirements, coding and pricing guidelines, as well as national and local coverage determinations and clinical evidence.

## *BILLING GUIDELINES AND CODING*

**GENERAL**

Prior to January 1, 2017, there were no specific codes available for an implantable magnetic esophageal ring (e.g., LINX® Reflux Management System) and unlisted codes were used. Effective January 1, 2017, CPT codes 43284 and 43285 were implemented and should now be used.

| CODES* | | |
|---|---|---|
| **CPT** | 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 |
| **HCPCS** | None | |

***Coding Notes:**

- The code list above is provided as a courtesy and may not be all-inclusive. Inclusion or omission of a code from this policy neither implies nor guarantees reimbursement or coverage. Some codes may not require routine review for medical necessity, but they are subject to provider contracts, as well as member benefits, eligibility and potential utilization audit. According to Medicare, "presence of a payment amount in the MPFS and the Medicare physician fee schedule database (MPFSDB) does not imply that CMS has determined that the service may be covered by Medicare." The issuance of a CPT or HCPCS code or the provision of a payment or fee amount by Medicare does **not** make a procedure medically reasonable or necessary or a covered benefit by Medicare. *(Medicare Claims Processing Manual, Chapter 23 - Fee Schedule Administration and Coding Requirements, §30 - Services Paid Under the Medicare Physician's Fee Schedule, A. Physician's Services)*
- All unlisted codes are reviewed for medical necessity, correct coding, and pricing at the claim level. If an unlisted code is submitted for non-covered services addressed in this policy then it will be **denied as not covered**. If an unlisted code is submitted for potentially covered services addressed in this policy, to avoid post-service denial, **prior authorization is recommended**.
- **See the non-covered and prior authorization lists on the Company Medical Policy, Reimbursement Policy, Pharmacy Policy and Provider Information website for additional information.**
- HCPCS/CPT code(s) may be subject to National Correct Coding Initiative (NCCI) procedure-to-procedure (PTP) bundling edits and daily maximum edits known as "medically unlikely edits" (MUEs) published by the Centers for Medicare and Medicaid Services (CMS). This policy does not take precedence over NCCI edits or MUEs. Please refer to the CMS website for coding guidelines and applicable code combinations.

## *REFERENCES*


1. CMS Proposed Rule CMS-1734-P; Available at: https://www.federalregister.gov/documents/2020/08/17/2020-17127/medicare-program-cy-2021-payment-policies-under-the-physician-fee-schedule-and-other-changes-to-part. Accessed: 5/1/2024.


## *POLICY REVISION HISTORY*

| DATE | REVISION SUMMARY |
|---|---|
| 7/2023 | New Medicare Advantage medical policy |
| 8/2024 | Annual review; update criteria for removal of a magnetic esophageal ring when necessary for medically necessary reasons |