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#### **INSTRUCTIONS FOR USE DISCLAIMER:**

SummaCare posts policies relating to coverage and medical necessity issues to assist members and providers in administering member benefits. These policies do not constitute a contract or agreement between SummaCare and any member or provider. The policies are guidelines only and are intended to assist members and providers with coverage issues. SummaCare is not a health care provider, does not provide or assist with health care services or treatment, and does not make guarantees as to the effectiveness of treatment administered by providers. The treatment of members is the sole responsibility of the treating provider, who is not an employee of SummaCare, but is an independent contractor in private practice. The policies posted to this site may be updated and are subject to change without prior notice to members or providers.

Medical policies in conjunction with other nationally recognized standards of care are used to make medical coverage decisions.

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### **LINX Reflux Management System Policy**

#### **Indication/Usage:**

LINX Reflux Management System - Implantation of anti-gastroesophageal reflux device uses a small flexible band of interlinked titanium beads with magnetic cores that are laparoscopically placed around the esophagus, just above the stomach. The LINX system purportedly expands by swallowing, allowing food and liquid to pass normally into the stomach. The magnetic attraction then closes the LES, supposedly preventing reflux.

LINX has not been established as an effective option for the treatment of GERD and other indications.

The majority of the surveyed commercial payers consider this therapy as experimental, investigational, or unproven; therefore reimbursement issues may continue to negatively impact the full adoption of this procedure. (Hayes 2021)

#### **Medical Indications for Authorization Commercial Members**

SummaCare considers the LINX Reflux Management System (a sphincter augmentation device) (Ethicon, Bridgewater, NJ) experimental and investigational for the management of GERD and all other indications because it has not been established as an effective option for the treatment of GERD and other indications.

**Medicare Members CMS NCD ID 100.9 Implantation of Anti-Gastroesophageal Reflux Device** National Government Services

*Rev.10838, Issued, 06-08-21 Effective: 01-01-21, Implementation 06-22-21)* Effective January 1, 2021, the Centers for Medicare & Medicaid Services determined that no national coverage determination (NCD) is appropriate at this time for FDG PET for Implantation of Gastrointestinal Reflux Devices. In the absence of an NCD, coverage determinations will be made by the Medicare Administrative Contractors under 1862(a) (1) (A) of the Social Security Act.

**LCD L35080 Select Minimally Invasive GERD Procedures Coverage Guidance**

**Coverage Indications, Limitations, and/or Medical Necessity**

**Indications:** Coverage is not available for LINX® Reflux Management System, which is not a true endoluminal treatment but is also not considered reasonable and necessary for the diagnosis or treatment of an injury or disease.

**Limitations**

LINX Reflux Management System is a non-covered procedure

**Coverage Decisions**

Coverage decisions made per CMS Guidelines, Hayes Research and industry standards research

**Plans Covered By This Policy**

Commercial and Medicare

Considered experimental and investigational for all lines of business

**Sources Reviewed**

<https://www.cms.gov/medicare>

LCD - Select Minimally Invasive GERD Procedures (L35080) (cms.gov)

<https://www.cms.gov/medicare>

NCD - Implantation of Anti-Gastroesophageal Reflux Device (100.9) (cms.gov)

Hayes Knowledge Center | symplr (hayesinc.com)

Ajmera K, Thaimuriyil N, Shah N. Recent advances in the endoscopic management of gastroesophageal reflux disorder: A review of literature. *Cureus*. 2022; 14(6):e26218.

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