

Magnetic Esophageal Ring to Treat Gastroesophageal Reflux Disease (LINX)

Policy ID:	HHO-DE-MP-1023
Approved By:	Highmark Health Options – Market Leadership
Provider Notice Date:	
Original Effective Date:	N/A
Annual Approval Date:	09/2022
Last Revision Date:	09/20/2021
Products:	Medicaid
Application:	All participating hospitals and providers
Page Number(s):	1 of 4

Disclaimer

Highmark Health Options medical policy is intended to serve only as a general reference resource regarding coverage for the services described. This policy does not constitute medical advice and is not intended to govern or otherwise influence medical decisions.

POLICY STATEMENT

Highmark Health Options may provide coverage under medical surgical benefits of the Company's Medicaid products for medically necessary magnetic esophageal ring to treat gastroesophageal reflux disease (LINX).

This policy is designed to address medical necessity guidelines that are appropriate for the majority of individuals with a particular disease, illness or condition. Each person's unique clinical circumstances warrant individual consideration, based upon review of applicable medical records.

The qualifications of the policy will meet the standards of the National Committee for Quality Assurance (NCQA) and the Delaware Department of Health and Social Services (DHSS) and all applicable state and federal regulations.

DEFINITIONS

Highmark Health Options (HHO) – Managed care organization serving vulnerable populations that have complex needs and qualify for Medicaid. Highmark Health Options members include individuals and families with low income, expecting mothers, children, and people with disabilities. Members pay nothing to very little for their health coverage. Highmark Health Options currently services Delaware Medicaid: Delaware Healthy Children Program (DHCP) and Diamond State Health Plan Plus members.

Gastroesophageal Reflux Disease (GERD) – A digestive disorder that occurs when acidic stomach juices, or food and fluids back up from the stomach into the esophagus.

Laparoscopic implantable magnetic esophageal ring (LINX) – A ring composed of interlinked titanium beads with magnetic cores has been developed for the treatment of gastroesophageal reflux disease (GERD). The device is placed around the esophagus at the level of the gastroesophageal junction in individuals who have GERD symptoms despite maximum medical therapy.

PROCEDURES

1. A laparoscopically implantable magnetic esophageal ring (LINX® Reflux Management System) may be considered medically necessary when ALL of the following conditions are met:
 - When used as an alternative treatment to surgical fundoplication; and
 - When the individual presents with gastroesophageal reflux disease (GERD) and is symptomatic two (2) or more times per week; and
 - Who have GERD symptoms despite medical therapy or are intolerant to medical therapy.
2. Use of the laparoscopically implantable magnetic esophageal ring (LINX® Reflux Management System) for any other indication is considered experimental/investigational and therefore, non-covered because the safety and/or effectiveness of this service cannot be established by the available published peer reviewed literature.
3. Post-payment Audit Statement

The medical record must include documentation that reflects the medical necessity criteria and is subject to audit by Highmark Health Options at any time pursuant to the terms of your provider agreement.

4. Place of Service

Experimental/investigational (E/I) services are not covered regardless of place of service.

The use of a magnetic esophageal ring to treat gastroesophageal reflux disease (LINX®) is typically an outpatient procedure which is only eligible for coverage as an inpatient procedure in special circumstances, including, but not limited to, the presence of a comorbid condition that would require monitoring in a more controlled environment such as the inpatient setting.

CODING REQUIREMENTS

CPT code	Description
43284	Laparoscopy, surgical, esophageal sphincter augmentation procedure, placement of sphincter augmentation device (i.e. magnetic band), including cruroplasty when performed.
43285	Removal of esophageal sphincter augmentation device.
43289	Unlisted laparoscopy procedure, esophagus.

Diagnosis codes

Code	Description
K21.00	Gastroesophageal reflux disease with esophagitis, without bleeding.
K21.01	Gastroesophageal reflux disease with esophagitis, with bleeding.
K21.9	Gastroesophageal reflux disease without esophagitis.

REIMBURSEMENT

Participating facilities will be reimbursed per their Highmark Health Options contract.

References

- American Academy of Allergy, Asthma, and Immunology. (2021). Gastroesophageal Reflux Disease. Retrieved from <https://www.aaaai.org/Conditions-Treatments/related-conditions/gastroesophageal-reflux-disease>.
- Sheu E, Nau P, Nath B, et al. A comparative trial of laparoscopic magnetic sphincter augmentation and Nissen fundoplication. *Surg Endo*. 2015;29:505–509.
- Riegler M, Schoppman S, Bonavina L, et al. Magnetic sphincter augmentation and fundoplication for gastroesophageal reflux disease (GERD) in clinical practice: One-year results of a multicenter, prospective observational study. *Surg Endo*. 2015;29:1123–1129.
- Ganz RA, Edmundowicz SA, Taiganides PA, et al. Long-term outcomes of patients receiving a magnetic sphincter augmentation device for gastroesophageal reflux. *Clin Gastroenterol Hepatol*. 2015;(14):671–677.
- Reynolds JL, Zehetner J, Wu P, Shah S, Bildzukewicz N, Lipham JC. Laparoscopic magnetic sphincter augmentation vs laparoscopic nissen fundoplication: a matched-pair analysis of 100 patients. *J Am Coll Surg*. 2015;221:123-128.
- Schwaitzberg, SD. Surgical management of gastroesophageal reflux in adults. UpToDate. Last updated August 2016.
- Asti E, Bonitta G, Lovece A, Lazzari V, Bonavina L. Longitudinal comparison of quality of life in patients undergoing laparoscopic Toupet fundoplication versus magnetic sphincter augmentation: observational cohort study with propensity score analysis. *Medicine*. 2016;95(30).
- Hayes, Inc. Health Technology Brief. Magnetic Sphincter Augmentation (LINX Reflux Management System) for Treatment of Gastroesophageal Reflux Disease. Lansdale, PA: Hayes, Inc.; January, 2020.
- Skubleny D, Switzer N, Dang J, et al. LINX magnetic esophageal sphincter augmentation versus Nissen fundoplication for gastroesophageal reflux disease: a systemic review and meta-analysis. *Surg Endosc*. 2017;31:3078-3084.
- Desart K, Rossidis G, Michet M, Lux T. Gastroesophageal reflux management with the LINX system for gastroesophageal reflux disease following laparoscopic sleeve gastrectomy. *J Gastrointest Surg*. 2015;19:1782-1786.
- Zadeh J, Andreoni A, Treitl D, et al. Spotlight on the Linx™ Reflux Management System for the treatment of gastroesophageal reflux disease: evidence and research. *Med Devices*. 2018;11:291-300.
- Warren HF, Reynolds JL, Lipham JC, et al. Multi-institutional outcomes using magnetic sphincter augmentation versus Nissen fundoplication for chronic gastroesophageal reflux disease. *Surg Endosc*. 2016;30(8):3289-3296.
- American Society of General Surgeons (ASGS). LINX Statement of Support from ASGS. 2014. Accessed July 2, 2020.
- SAGES: Society of American Gastrointestinal and Endoscopic Surgeons (SAGES). TAVAC Category: Safety and Effectiveness. LINX Reflux Management System. 2017; <https://www.sages.org/publications/tavac/tavac-safety-and-effectiveness-analysis-linx-refluxmanagement-system/>. Accessed July 2, 2020.

Guidozzi N, Wiggins T, Ahmed AR, Hanna GB, Markar SR. Laparoscopic magnetic sphincter augmentation versus fundoplication for gastroesophageal reflux disease: systematic review and pooled analysis. *Dis Esophagus*. 2019;32(9):doz031.

Aiolfi A, Asti E, Bernardi D, et al. Early results of magnetic sphincter augmentation versus fundoplication for gastroesophageal reflux disease: Systematic review and meta-analysis. *Int J Surg*. 2018;52:82-8.

POLICY UPDATE HISTORY

<Date>	<Event>
--------	---------