

n05568

Medical Policy – LINX Reflux Management System

Values

Accountability • Integrity • Service Excellence • Innovation • Collaboration

Abstract Purpose:

The purpose of this policy is to provide guidance for Network Health Plan/Network Health Insurance Corporation/Network Health Administrative Services, LLC's (NHP/NHIC/NHAS) utilization management teams regarding medical necessity decisions related to the implantation of the LINX Reflux Management System requests.

Policy Detail:

Refer to the appropriate Certificate of Coverage, Evidence of Coverage, Summary Plan Description, Individual and Family Policy or It's Your Choice booklet to determine eligibility and coverage because Employer Group/Plan Sponsor and government contracts may vary.

I. Description

A. Gastroesophageal reflux disease (GERD), commonly manifested by heartburn or regurgitation, is a digestive disorder that affects the lower esophageal sphincter (LES), the ring of muscle between the esophagus and the stomach. It is a chronic, progressive condition in which failed sphincter function allows the contents of the stomach to reflux into the esophagus, the airways and the mouth. The most important treatment of GERD is lifestyle and dietary changes. The majority of patients receive adequate relief from those changes along with using different medications, such as antacids. In addition, many individuals receive relief from proton pump inhibitors (PPIs), but some patients have incomplete relief of symptoms that cannot be addressed by increasing the dose of medications and surgical procedures are needed in these situations. Nissen Fundoplication (NF) involves wrapping the fundus of the stomach around the lower esophagus to reduce GERD. NF can be performed as an open procedure or laparoscopically. An endoscopic option for the treatment of GERD is Transoral Incisionless Fundoplication (TIF). The LINX Reflux Management System is an FDA approved device implanted laparoscopically for the treatment of GERD. The system relies on a flexible "bracelet" of magnetic titanium beads that, when placed around the esophagus, augment and strengthen an ineffective lower esophageal sphincter, the muscle that opens and closes to allow food to enter and stay in the stomach by restoring the body's natural barrier to reflux.

II. Medical Indicators/Criteria:

- A. Network Health considers the use of surgical Nissen fundoplication for the treatment of GERD as medically necessary when:
1. An existing MCG guideline is met for the specific material and indication requested.

- B. The following criteria for the implantation of LINX Reflux Management System is considered medically necessary when **ALL** criteria are met:
1. The implantation of an anti-gastroesophageal reflux device is covered only for patients with documented severe or life threatening gastroesophageal reflux disease whose conditions have been resistant to medical treatment and who also:
 - a. Have esophageal involvement with progressive systemic sclerosis; **OR**
 - b. Have foreshortening of the esophagus such that insufficient tissue exists to permit a valve reconstruction; **OR**
 - c. Are poor surgical risks for a valvuloplasty procedure; **OR**
 - d. Have failed previous attempts at surgical treatment with valvuloplasty procedures, **AND**
 2. There is objective documentation of reflux and/or esophagitis via endoscopy. If endoscopy is normal, objective evidence of reflux should include at least one (1) of the following:
 - a. 24-hour ambulatory esophageal pH monitoring **OR**
 - b. Barium swallow study **AND**
 3. Lifestyle modifications symptoms are unresponsive to two (2) or more of the following lifestyle modifications:
 - a. Weight loss for overweight or obese patients; **OR**
 - b. Avoidance of late meals and/or specific foods that cause heartburn (spicy foods, citrus, fatty foods, chocolate, caffeine, carbonated drinks, alcohol, etc.); **OR**
 - c. Elevation of the head of the bed for patients who develop heartburn or regurgitation when lying down; **OR**
 - d. Avoidance of recumbent position within 2-3 hours after a meal; **AND**
 4. The individual has a documented six (6)-month trial of proton pump inhibitors (PPIs), including at least two (2) different PPIs, which are ineffective, contraindicated or not tolerated; **AND**
 5. The individual is a candidate for fundoplication surgery but LINX is being chosen instead; **AND**
 6. The individual does not have evidence of:
 - a. Barrett's Esophagus
 - b. Motility and/or swallowing issues
 - c. Previous bariatric surgery
 - d. Morbid obesity with a body mass index > 35 kg/m² at the time of the surgical assessment for the procedure
 - e. Significant hiatal hernia $> three$ (3) cm as defined by manometry, upper GI (barium swallow), or endoscopy (one of these measurements should be three (3)-cm or less)
 - f. Allergy to titanium, stainless steel, nickel or iron materials; **AND**
 7. The patient has completed a shared decision making information session prior to the procedure to improve patient satisfaction, increase patient's knowledge of their condition, and assess readiness to make behavior changes. This shared decision making session should include instruction including but not limited to:
 - a. Explanation of the upcoming procedure and surgery
 - b. Risks and benefits of the procedure/surgery
 - c. How to manage the chronic condition
 - d. General healthcare expectations
 - e. Alternatives to the procedure/surgery

- III. Coverage:
- A. The use of surgical treatment for GERD is a covered benefit when deemed medically necessary per the criteria listed above.
 - B. NHIC follows CMS National Coverage Determinations (NCD) and Local Coverage Determinations (LCD) for application to its Medicare Advantage membership. (LCD L35080 Select Minimally Invasive GERD Procedures.)
- IV. Limitations/Exclusions:
- A. The use of surgical treatment for GERD for all indications other than outlined above will be reviewed under Network Health's experimental, investigational and/or unproven process.
- V. References:
- A. Aiolf, A, Asti, E, Bernardi, D, Bonitta, G, Rausa, E, Siboni, S & Bonavina L. Early Results of Magnetic Sphincter Augmentation Versus Fundoplication for Gastroesophageal Reflux Disease: Systematic Review and Meta-Analysis. PMID: 29471155 DOI: 10.1016/j.ijsu.2018.02.041
 - B. Bell, R, Lipham, J, Louie, B, Williams, V, Luketich, J, Hill, M, Richards, W, Dunst, C, Lister, D, McDowell-Jacobs, L, Reardon, P, Woods, K, Gould, J, Buckley, FP 3rd, Kothari, S, Khaitan, L, Smith, CD, Park, A, Smith, C, Jacobsen, G, Abbas, G & Katz, P. Laparoscopic Magnetic Sphincter Augmentation Verses Double-Dose Proton Pump Inhibitors for Management of Moderate-to-Severe Regurgitation in GERD: A Randomized Controlled Trial. Gastrointestinal Endosc 2019 Jan;89(1):14-22. DOI: 10.1016/j.gie.2018.07.007 Epub 2018 Jul 18.
 - C. Johnson & Johnson Medical Devices Companies, Linx Reflux Management System. www.jnjmedicaldevices.com. Website accessed 03/10/2021
 - D. Local Coverage Determination (LCD) for Select Minimally Invasive GERD Procedures(L35080)
 - E. MCG Ambulatory Care 25th edition Implantable Magnetic Esophageal Ring (LINX) ACG: A-0990
 - F. National Coverage Determination (NCD) for Implantation of Anti-Gastroesophageal Reflux Device (100.9)
 - G. Schwaitzberg, SD. Surgical Management of Gastroesophageal Reflux in Adults. UpToDate Literature review current through February 2020

Regulatory Citations:

UM 2

Related Policies:

None

Related Documents:

None

CPT Codes:*

43284	Laparoscopy, surgical, esophageal sphincter augmentation procedure, placement of sphincter augmentation device (i.e., magnetic band), including cruroplasty when performed, for the LINX implantation procedure performed with the hiatal hernia repair.
43285	Removal of Esophageal sphincter augmentation device
*CPT codes are subject to change as codes are retired or new ones developed.	

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Policy Owner: Tori Kirby	Department of Ownership: Utilization Management	Revision Number: 5
Revision Reason: Annual review: 5/18/2017 10/14/16: Transferred to new template. 05/18/2017: annual review 05/18/2018: annual review 05/16/2019: annual review 04/16/2020: annual review references updated 05/01/2021: annual review, references updated, CPT codes added		

Disclaimer:

Contract language as well as state and federal laws take precedence over any medical policy. Network Health coverage documents (i.e. Certificate of Coverage, Evidence of Coverage, Summary Plan Descriptions) outline contractual terms of the applicable benefit plan for each line of business and will be considered first in determining eligibility. Not all Network Health coverage documents are the same. Coverage may differ. Our Medicare membership follows applicable Centers for Medicare and Medicaid Services (CMS) coverage statements including National Coverage Determinations (NCD) and Local Coverage Determinations (LCD). Please refer to the CMS website at www.cms.gov.

Network Health reserves the right to review and update our medical policies on occasion as medical technologies are constantly evolving. The documentation of any brand name of a test, product and/or procedure in a medical policy is in no way an endorsement of that product; it is for reference only.

Network Health's medical policies are for guidance and not intended to prevent the judgment of the reviewing medical director(s) nor dictate to health care providers how to practice medicine.