Geisinger

Geisinger Health Plan Policies and Procedure Manual

Policy: MP315

Section: Medical Benefit Policy

Subject: Magnetic Esophageal Sphincter Augmentation (LINX)

Applicable Lines of Business

Commercial	**X**	**CHIP**	**X**
Medicare	**X**	**ACA**	**X**
Medicaid	**X**		

I. Policy: Magnetic Esophageal Sphincter Augmentation

II. Purpose/Objective:

To provide a policy of coverage regarding Magnetic Esophageal Sphincter Augmentation

III. Responsibility:

A. Medical Directors
B. Medical Management

IV. Required Definitions

1. Attachment – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. Exhibit – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. Devised – the date the policy was implemented.
4. Revised – the date of every revision to the policy, including typographical and grammatical changes.
5. Reviewed – the date documenting the annual review if the policy has no revisions necessary.

V. Additional Definitions

Medical Necessity or Medically Necessary means Covered Services rendered by a Health Care Provider that the Plan determines are:

a. appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
b. provided for the diagnosis, and the direct care and treatment of the Member's condition, illness disease or injury;
c. in accordance with current standards of good medical treatment practiced by the general medical community.
d. not primarily for the convenience of the Member, or the Member's Health Care Provider; and
e. the most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

Medicaid Business Segment

Medically Necessary — A service, item, procedure, or level of care that is necessary for the proper treatment or management of an illness, injury, or disability is one that:

- Will, or is reasonably expected to, prevent the onset of an illness, condition, injury or disability.
- Will, or is reasonably expected to, reduce or ameliorate the physical, mental or developmental effects of an

illness, condition, injury or disability.
- Will assist the Member to achieve or maintain maximum functional capacity in performing daily activities, taking into account both the functional capacity of the Member and those functional capacities that are appropriate for Members of the same age

DESCRIPTION:
LINX is an FDA-approved magnetic sphincter augmentation device composed of a series of magnets set in titanium casing and connected by titanium wires laparoscopically implanted to augment lower esophageal function in patients with gastroesophageal reflux disease refractory to nonsurgical medical therapy and maximized pharmacologic therapy. The magnetic sphincter augmentation device is an alternative to Nissen fundoplication which is an irreversible creation of a non-physiologic sphincter that prohibits belching and vomiting**.**

INDICATIONS: REQUIRES PRIOR AUTHORIZATION BY A PLAN MEDICAL DIRECTOR OR DESIGNEE

Magnetic esophageal sphincter augmentation is considered medically necessary when all of the following criteria are met:

- The member has medical record documentation of a diagnosis of GERD; and
- Medical record documentation that disease is refractory to:
  - Documented reasonable attempts at weight loss if BMI ≥30
  - Diet modification
  - maximized PPI treatment
- Disease requires long-term therapy; and
- Pre-operative manometry has eliminated the diagnosis of achalasia or scleroderma-like esophagus; and
- Ambulatory pH monitoring has been completed in members without evidence of erosive esophagitis

This service may be considered on a “per case” basis through the Program Exception process for the Medicaid business segment.

Medicaid Business Segment:
This service may be considered on a “per case” basis through the Program Exception process for the Medicaid business segment.

Any requests for services, that do not meet criteria set in the PARP, may be evaluated on a case by case basis

Medicare Business Segment:

This service is considered “Not Reasonable and Necessary” for the Medicare business segment per LCD L35094Services That Are Not Reasonable and Necessary

Note: A complete description of the process by which a given technology or service is evaluated and determined to be experimental, investigational or unproven is outlined in MP 15 - Experimental Investigational or Unproven Services or Treatment.

CODING ASSOCIATED WITH: Magnetic Esophageal Sphincter Augmentation
The following codes are included below for informational purposes and may not be all inclusive. Inclusion of a procedure or device code(s) does not constitute or imply coverage nor does it imply or guarantee provider reimbursement. Coverage is determined by the member specific benefit plan document and any applicable laws regarding coverage of specific services. Please note that per Medicare coverage rules, only specific CPT/HCPCS Codes may be covered for the Medicare Business Segment. Please consult the CMS website at www.cms.gov ***or the local Medicare Administrative Carrier (MAC) for more information on Medicare coverage and coding requirements.***

43284 Laparoscopy, surgical, esophageal sphincter augmentation procedure, of sphincter augmentation device (i.e. magnetic band), including cruroplasty when performed
43285 Removal of esophageal sphincter augmentation device
L8699 Prosthetic implant, not otherwise specified
A4649 Surgical supply, miscellaneous

Current Procedural Terminology (CPT®) © American Medical Association: Chicago, IL

LINE OF BUSINESS:

Eligibility and contract specific benefits, limitations and/or exclusions will apply. Coverage statements found in the line of business specific benefit document will supersede this policy. For Medicare, applicable LCD's and NCD's will supercede this policy. For PA Medicaid Business segment, this policy applies as written.

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This policy will be revised as necessary and reviewed no less than annually.

Devised: 3/17

Revised: 12/19 (Clarified Medicare non-coverage)

Reviewed: 3/18**,** 3/19, 12/20, 12/21, 12/22, 12/23

Geisinger Health Plan may refer collectively to health care coverage sponsors Geisinger Health Plan, Geisinger Quality Options, Inc., and Geisinger Indemnity Insurance Company, unless otherwise noted. Geisinger Health Plan is part of Geisinger, an integrated health care delivery and coverage organization.

Coverage for experimental or investigational treatments, services and procedures is specifically excluded under the member's certificate with Geisinger Health Plan. Unproven services outside of an approved clinical trial are also specifically excluded under the member's certificate with Geisinger Health Plan. This policy does not expand coverage to services or items specifically excluded from coverage in the member's certificate with Geisinger Health Plan. Additional information can be found in MP015 Experimental, Investigational or Unproven Services.

Prior authorization and/or pre-certification requirements for services or items may apply. Pre-certification lists may be found in the member's contract specific benefit document. Prior authorization requirements can be found at https://www.geisinger.org/health-plan/providers/ghp-clinical-policies

Please be advised that the use of the logos, service marks or names of Geisinger Health Plan, Geisinger Quality Options, Inc. and Geisinger Indemnity Insurance Company on a marketing, press releases or any communication piece regarding the contents of this medical policy is strictly prohibited without the prior written consent of Geisinger Health Plan. Additionally, the above medical policy does not confer any endorsement by Geisinger Health Plan, Geisinger Quality Options, Inc. and Geisinger Indemnity Insurance Company regarding the medical service, medical device or medical lab test described under this medical policy.