TITLE: MAGNETIC ESOPHAGEAL RING FOR THE TREATMENT OF GASTROESOPHAGEAL REFLUX DISEASE

EFFECTIVE DATE: November 19, 2018

This policy was developed with input from specialists in gastroenterology and endorsed by the Medical Policy Committee.

IMPORTANT INFORMATION – PLEASE READ BEFORE USING THIS POLICY
These services may or may not be covered by all Medica plans. Please refer to the member’s plan document for specific coverage information. If there is a difference between this general information and the member’s plan document, the member’s plan document will be used to determine coverage. With respect to Medicare and Minnesota Health Care Programs, this policy will apply unless these programs require different coverage. Members may contact Medica Customer Service at the phone number listed on their member identification card to discuss their benefits more specifically. Providers with questions about this Medica utilization management policy may call the Medica Provider Service Center toll-free at 1-800-458-5512.

Medica utilization management policies are not medical advice. Members should consult with appropriate health care providers to obtain needed medical advice, care and treatment.

PURPOSE
To promote consistency between reviewers in utilization management decision-making by providing the criteria that generally determine the medical necessity of magnetic esophageal ring for gastroesophageal reflux disease. The Benefit Considerations box below outlines the process for addressing the needs of individuals who do not meet these criteria.

BACKGROUND
Definitions
A. Barrett’s Esophagus is a condition in which the tissue of the lower esophagus is replace with columnar epithelium as a result of chronic reflux, and is associated with an increased risk of esophageal cancer.
B. The esophageal sphincter is the circular band of muscle that closes the distal portion of the esophagus, thus preventing the backward flow of stomach contents.
C. An esophageal pH test is a procedure done to measure the amount of acid the flows into the esophagus from the stomach during a 24-hour period.
D. Gastroesophageal Reflux Disease (GERD) occurs when stomach contents back up into the esophagus, causing heartburn (acid reflux) and/or chest pain. GERD is a common condition and has a prevalence of 10-20% in the Western world. Symptoms of GERD also may include difficulty swallowing, a dry cough, hoarseness, and sore throat.
E. A hiatal hernia is a condition in which the upper part of the stomach bulges through an opening in the diaphragm, which may allow acid to reflux into the esophagus.
F. Magnetic esophageal sphincter augmentation, also known as LINX Reflux Management System, is intended to treat chronic gastroesophageal reflux disease (GERD) by the implantation of a ring that fits around the esophagus to prevent reflux of bile and acid from the stomach into the esophagus. Swallowing forces temporarily break in the magnetic bond, and food and liquid are allowed to pass normally into the stomach.

BENEFIT CONSIDERATIONS
1. Prior authorization is required for magnetic esophageal ring for the treatment of gastroesophageal reflux disease.
2. The procedure is to be performed by a surgeon who has received specific training in the placement of the LINX...
3. Coverage may vary according to the terms of the member’s plan document.
4. Magnetic esophageal ring is investigative and therefore, not covered for all other indications, including but not limited to, Barrett’s Esophagus.
5. If the Medical Necessity and Coverage Criteria are met, Medica will authorize benefits within the limits in the member’s plan document.
6. If it appears that the Medical Necessity and Coverage Criteria are not met, the individual’s case will be reviewed by the medical director or an external reviewer. Practitioners are reminded of the appeals process in their Medica Provider Administrative Manual.

MEDICAL NECESSITY CRITERIA
I. Indications
   Magnetic esophageal sphincter augmentation is considered medically necessary when documentation in the medical record shows all of the following criteria are met:
   A. There is objective evidence of GERD, defined by one of the following:
      1. An abnormal pH study
      2. Dysplasia as evidenced by endoscopy.
   B. The member has a diagnosis of refractory GERD, as evidenced by all of the following:
      1. Failure of PPI medication
      2. Failure of other nonsurgical treatments such as weight loss, smoking cessation, and avoidance of trigger foods.
   II. No documented contraindications present as indicated by all of the following:
      A. No suspected or known allergies to titanium, stainless steel, nickel, or ferrous materials
      B. No implanted devices such as defibrillators or pacemakers
      C. No hiatal hernia greater than 3 cm in size.
   III. Written documentation in the medical record must include a description of all trials of conservative therapy including the length and results of treatment.

CENTERS FOR MEDICARE & MEDICAID SERVICES (CMS)
- For Medicare members, refer to the following, as applicable at: http://www.cms.hhs.gov/mcd/search.asp?

DOCUMENT HISTORY
<table>
<thead>
<tr>
<th>Original Effective Date</th>
<th>November 20, 2017</th>
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<tbody>
<tr>
<td>MPC Endorsed Date(s)</td>
<td>09/2017, 09/2018</td>
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<tr>
<td>Administrative Updates</td>
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</tbody>
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References:
Pre-01/2016 MTAC:
6. National Horizon Scanning Centre. LINX reflux management system for gastro-esophageal reflux disease (GORD). Horizon Scanning Review. Birmingham, UK. National Horizon Scanning Centre (NHSC); April 2011.

01/2016 MTAC:


03/2017 MTAC:


09/2017 MPC:


09/2018 MPC:


42. Schwaitzberg SD. Surgical management of gastroesophageal reflux in adults. Last updated July 2018. In: *UpToDate*, Friedberg, SJ (Ed), UpToDate, Waltham, MA, 2018