HEALTH TRADITION P.O. Box 21171 | Eagan, Minnesota 55121 | 877.832.1823 | healthtradition.com

Medical Policy

Treatment of Gastroesophageal Reflux Disease including Laparoscopic Fundoplication and Linx Reflux Management System

Policy Number: 1016

Policy History			
Approve Date:	06/01/2018	Effective Date:	06/01/2018
Reviewed/Revised Date:	05/09/2019, 04/14/2020, 04/14/2021		

Preauthorization	
All Plans	Benefit plans vary in coverage and some plans may not provide coverage for certain service(s) listed in this policy. Decisions for authorization are subject to all terms and conditions of the applicable benefit plan, including specific exclusions and limitations as well as applicable state and/or federal laws. Please review the benefit plan descriptions for details.

Policy

Indications of Coverage

I. WEA Trust considers laparoscopic esophagogastric fundoplasty medically necessary for ANY of the following indications:
   A. Symptomatic gastroesophageal reflux disease (GERD) (e.g., heartburn, regurgitation, hoarseness, cough) unresponsive to medication therapy (at least six months) and lifestyle modification
   B. GERD with the development of Barrett's esophagus with metaplasia, low-grade dysplasia, stricture, or esophageal ulcer
   C. GERD after endoscopic therapy of Barrett's esophagus with high-grade dysplasia or adenocarcinoma
   D. Surgical alternative to anticipated long-term use of proton pump inhibitor (PPI) (12 months or longer)
   E. Achalasia with stricture formation from reflux (in conjunction with esophageal myotomy)
   F. Procedure is coincident with paraesophageal hernia repair OR
   G. Repeat surgery for failed anti-reflux procedures.

   Note: Esophagogastric fundoplasty is not recommended for members who are morbidly obese (body mass index greater than 35 kg/m^2) due to high failure rates.

II. WEA Trust considers the following treatment devices for GERD and other indications not medically necessary. They are experimental and investigational because effectiveness has not been established:
   A. Bard EndoCinch Suturing System
   B. Esophyx
   C. StomaphyX
   D. Stretta System
   E. Angelchik anti-reflux prosthesis
   F. Enteryx injections
   G. Endoscopic Plicator System

H. Syntheon ARD Plicator
I. Durasphere
J. Gatekeeper Reflux Repair System
K. Plexiglas polymethylmethacrylate microspheres

III. WEA Trust considers Linx Reflux Management System medically necessary when the follow criteria are met:
A. Member must be at least 18 years old and less than 74 years old with a life expectancy of >3 years AND
B. Is a suitable surgical candidate as defined by able to undergo general anesthesia and laparoscopic surgery AND
C. Has documented symptoms of gastroesophageal reflux disease for longer than six months AND
D. Requires daily proton pump inhibitor or other anti-reflux drug therapy AND
E. Total Distal Ambulatory Esophageal ph must meet the following criteria:
i. PH <4 for 4.5% or more of the time following discontinuation of GERD medications at least seven days prior to testing.

IV. WEA Trust considers the following indications experimental and investigational and are considered not medically appropriate/necessary for the Linx procedure and are therefore not covered:
A. History of gastroesophageal surgery, anti-reflux procedures, or gastroesophageal/gastric cancer OR
B. Any previous endoscopy anti-reflux intervention for GERD, and/or previous endoscopic intervention for treatment for treatment of Barrett's esophagus OR
C. Suspected or confirmed esophageal or gastric cancer OR
D. Any sized hiatal hernia > 3 cm as determined by endoscopy it hiatal hernia repair to less than 3cm hernia is not planned in conjunction with LINX OR
E. Distal esophageal motility is less than 35 mm HG peristaltic amplitude on wet swallows or <70% (propulsive) peristaltic sequences OR
F. Esophagitis - Grade C or D OR
G. Diagnosed with an esophageal motility disorder such as, but not limited to achalasia, nutcracker esophagus, or diffuse esophageal spasm, or hyper tensive lower esophageal sphincter OR
H. Member has a history of or known esophageal stricture or gross esophageal anatomical abnormalities (Schatzki's ring, or obstructive lesions) OR
I. Member has esophageal or gastric varices OR
J. Member is pregnant or nursing or plans to become pregnant in the future OR
K. Medical illness that may cause the subject to be non-compliant with or unable to meet the protocol requirement or is associated with limited life expectancy (less than three years) OR
L. Diagnosed with psychiatric disorder such as bipolar or schizophrenia (Members that exhibit depression that are on appropriate medications(s) and meet previously mentioned criteria are allowable OR
M. Member with suspected or known allergies to titanium, stainless steel , nickel or ferrous materials OR
N. Member who have and electrical implant or metallic, abdominal implants

Background

Gastroesophageal reflux disease (GERD) is a common chronic digestive disease that occurs when stomach acid or, occasionally, bile refluxes into the esophagus. Reflux occurs when the lower esophageal sphincter (LES) does not close tight enough or opens too often allowing the flow of stomach acids into the esophagus causing pain and heartburn. Occasional heartburn is not serious but long term acid exposure can cause damage to the lining of the esophagus and lead to several complications which include Barrett’s esophagus, ulcers, strictures of esophagus, or cancer of the esophagus. The diagnosis of GERD is given when symptoms of acid reflux occur at least twice each week or interfere with a member’s daily life.

Mild heartburn and acid reflux can be managed with lifestyle and diet changes and over-the-counter medications. However, people with GERD may need prescription medications or even surgery. Lifestyle modifications include weight loss; avoidance of overeating, late night eating; and foods and beverages that cause heartburn; tobacco cessation; and elevating the head during sleep. Common medications to help manage the symptoms of GERD include antacids, Histamine-2 (H2) receptor antagonists (e.g., Pepcid, Tagamet, and Zantac), and proton pump inhibitors (PPI's) (e.g., Nexium, Prevacid, and Prilosec).

Surgery to treat chronic GERD may be appropriate if a member continues to experience symptoms despite treatment or is unable or unwilling to continue ongoing medical treatment. Surgical fundoplication involves wrapping a portion of the stomach fundus around the esophagus, thus increasing the pressure within the LES. The two most common procedures of this type are the Nissen fundoplication (a total fundal wrap) and the Toupet partial fundoplication. Nissen fundoplication is also performed to treat hiatal hernias with GERD symptoms. The surgery is usually performed laproscopically on an outpatient basis. Extended hospital stays may be indicated for higher risk patients (e.g., repair of paraesophageal hernia or large hiatal hernia) or if complications arise. Return to normal activities usually is within seven to ten days. The procedure can also be done in an open surgery, but the average length of hospital stay and recovery is significantly longer.

Efficacy rates of GERD surgeries are as high as 90%. Complications do exist and include dysphagia and inability to belch or vomit. Whether or not the benefits of fundoplication are maintained in the long term are not known at this time, but short and medium-term evidence from published studies indicate surgery is as effective as or more effective than long-term medication therapy. Repeat surgery may be indicated if the initial procedure fails and requires repair. Esophagogastric fundoplication is not recommended for members who are morbidly obese (body mass index greater than 35 kg/m2) due to high failure rates.

References

The above policy is based on the following references:

Milliman Care Guidelines:
1. ORG: S-505 (ISC) Fundoplasty, Esophagogastric, by Laparoscopy