



**Subject:** Endoscopic and Minimally Invasive Management of Gastroesophageal Reflux Disease (GERD)\*

**Effective Date:** April 24, 2007

**Department(s):** Utilization Management

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**Policy:** Endoscopic therapeutic interventions for GERD (ICD-9 530.11 or 530.81; ICD 10- K21.0, K21.9) are not reimbursable under Plans administered by QualCare, Inc.

**Objective:** To assure proper and consistent reimbursement and to exclude coverage of treatments not adequately supported by peer-reviewed literature.

**Procedure:**

1. Treatment of GERD with endoscopic devices will be denied coverage because there is not a satisfactory body of peer-reviewed literature that supports the efficacy of this approach to GERD.
2. CPT and HCPCS codes addressed by this policy include:
  - 43210- Endoscopic full-thickness plication of the gastric cardia
  - 43257 - EGD with application of thermal energy to muscle of the lower esophageal sphincter or gastric cardia for treatment of GERD
  - 43192, 43201( when used for treatment of GERD) injection of biocompatible material

- 43284, 43285-placement of esophageal sphincter augmentation device( i.e magnetic band)

3. Devices addressed by this policy include: Bard Endocinch Suturing System, EsophyX, StomaphyX. Enteryx, Plicator System, Stretta, and Gatekeeper Reflux Repair System, LINX™ Reflux Management System and Durasphere™.

## References

Hillman L, Yadlapati R, Whitsett M, Thuluvath AJ, et al. Review of antireflux procedures for proton pump inhibitor nonresponsive gastroesophageal reflux disease. *Dis Esophagus*. 2017 ;30(9):1-14(Sep)

Skubleny D, Switzer NJ, Dang J, Gill RS, Shi X, de Gara C, Birch DW, Wong C, Hutter MM, Karmali S. LINX® magnetic esophageal sphincter augmentation versus Nissen fundoplication for gastroesophageal reflux disease: a systematic review and meta-analysis. *Surg Endosc*. 2016 Dec 15. [Epub ahead of print]

Kim HJ, Kwon CI, Kessler WR, Selzer DJ, McNulty G, Bapaye A, Bonavina L, Lehman GA. Long-term follow-up results of endoscopic treatment of gastroesophageal reflux disease with the MUSE™ endoscopic stapling device. *Surg Endosc*. 2016;30(8):3402-8(Aug)

Hayes, Inc. Hayes Technology Brief. Magnetic Sphincter Augmentation (LINX Reflux Management System) for Treatment of Gastroesophageal Reflux Disease. Dec 10, 2015. Annual review Oct 31, 2016. Accessed at Hayesinc.com

Hayes Medical Technology Directory- Endoscopic Therapy for Gastroesophageal Reflux Disease, Annual Review August 5, 2016. Accessed at Hayesinc.com

Ganz RA, Edmundowicz SA, Taiganides PA, Lipham JC, et al. Long-Term Outcomes of Patients Receiving a Magnetic Sphincter Augmentation Device for Gastroesophageal Reflux. *Clin Gastroenterol Hepatol*. 2016;14(5):671-7(May)

Sheu EG, Nau P, Nath B, Kuo B, Rattner DW. A comparative trial of laparoscopic magnetic sphincter augmentation and Nissen fundoplication. *Surg Endosc*. 2015;29(3):505-9(Mar)

Hayes Medical Technology Directory- Endoscopic Therapy for Gastroesophageal Reflux Disease, July 30, 2015. Accessed at Hayesinc.com

Lipka S, Kumar A, Richter JE. No evidence for efficacy of radiofrequency ablation for treatment of gastroesophageal reflux disease: a systematic review and meta-analysis. *Clin Gastroenterol Hepatol.* 2015;13(6):1058-67(Jun).

Witteman BP, Conchillo JM, Rinsma NF, Betzel B, et al. Randomized controlled trial of transoral incisionless fundoplication vs. proton pump inhibitors for treatment of gastroesophageal reflux disease. *Am J Gastroenterol.* 2015;110(4):531-42(Apr)

Testoni PA, Testoni S, Mazzoleni G, Vailati C, Passaretti S. Long-term efficacy of transoral incisionless fundoplication with Esophyx (Tif 2.0) and factors affecting outcomes in GERD patients followed for up to 6 years: a prospective single-center study. *Surg Endosc.* 2015;29(9):2770-80 (Sep)

Hopkins J, Switzer NJ, Karmali S. Update on novel endoscopic therapies to treat gastroesophageal reflux disease: A review. *World J Gastro Endos.* 2015;7(11):1039-1044(Aug)

Triadafilopoulos,G. Radiofrequency treatment for gastroesophageal reflux disease.Version 9.0 UpToDate.com

Bell RC, Barnes WE, Carter BJ, Sewell RW, et al. Transoral incisionless fundoplication: 2-year results from the prospective multicenter U.S. study. *Am Surg.* 2014;80(11):1093-105(Nov)

Wendling MR, Melvin WS, Perry KA. Impact of transoral incisionless fundoplication(TIF) on subjective and objective GERD indices: a systematic review of the published literature. *Surg Endosc.* 2013;27(10):3754-61(Oct)

Auyang ED, Carter P, Rauth T, Fanelli RD. Endoluminal treatments for gastroesophageal Reflux Disease(GERD). Society of American Gastrointestinal and Endoscopic Surgeons Guidelines Committee. Accessed at sages.org

Katz PO, Gerson LB, Vela MF. Guidelines for the diagnosis and management of gastroesophageal reflux disease. *Am J Gastroenterol* 2013;108:308–328(Mar)

Perry AK, Banerjee A, Melvin WS. Radiofrequency energy delivery to the lower esophageal sphincter reduces esophageal acid exposure and improves GERD symptoms: a systematic review and meta-analysis. *Surg Laparosc Endosc Percutan Tech.* 2012;22(4):283-8(Aug)

Wittenam B, Strijkers R, de Vries E, Toeman L, et al. Transoral incisionless fundoplication for treatment of gastroesophageal reflux disease in clinical practice. *Surg Endosc.* 2012;26:3307-3315(May)

Muls V, Eckhardt AJ, Marchese M, Bastens B, et al. Three-year Results of a Multicenter Prospective Study of Transoral Incisionless Fundoplication. *Surg Innov.* 2012. Sep 11[Epub ahead of print]

Frazzoni M, Conigliaro R, Manta R, Melotti G. Reflux parameters as modified by EsophyX or laparoscopic fundoplication in refractory GERD. *Aliment Pharmacol Ther*. 2011 May 3 [epub ahead of print].

Flockens P, Cohen L, Edmundowicz SA, Binmoeller K, et al. Prospective randomized controlled trial of an injectable esophageal prosthesis versus a sham procedure for endoscopic treatment of gastroesophageal disease. *Surg Endosc*. 2010; 24(6):1387-1397 (June).

Von Renteln D, Brey U, Riecken B, et al. Endoscopic full-thickness plication (Plicator) with two serially placed implants improves esophagitis and reduces PPI use and esophageal acid exposure. *Endoscopy* 2008;40(3):173-178 (Mar)

Liao CC, Lee CL, Lin BR, et al. Endoluminal gastroplication for the treatment of gastroesophageal reflux disease: A 2-year prospective pilot study from Taiwan. *J Gastroenterol Hepatol* 2008;23(3):398-405 (Mar)

Pleskow D, Rothstein R, Kozarek R, et al. Endoscopic full-thickness plication for the treatment of GERD: Five-year long-term multicenter results. *Surg Endosc* 2008;22(2):326-332 (Feb)

Hayes, Inc. Hayes Medical Technology Directory. *Endoscopic Therapy for Gastroesophageal Reflux Disease*. Lansdale, PA. Hayes, Inc. October 22, 2007

Rothstein RI. Endoscopic therapy for gastroesophageal reflux disease: Sewing/plication techniques. *UpToDate* v 15.1 November 28, 2006. available at [www.udtol.com/utd/content/topic.do?topicKey=eso\\_dis/12982&view=print](http://www.udtol.com/utd/content/topic.do?topicKey=eso_dis/12982&view=print) accessed 03/05/07

Iqbal A, Salinas V, Filipi CJ. Endoscopic therapies of gastroesophageal reflux disease. *World J Gastroenterol* 2006;12(17):2641-2655 (May 7)

Liu JJ, Carr-Locke DL, Osterman MT, et al. Endoscopic treatment for atypical manifestations of gastroesophageal reflux disease. *Am J Gastroenterol* 2006;101(3):440-445 (Mar)

Mahmood Z, Byrne PJ, McMahon BP, et al. Comparison of transesophageal endoscopic plication (TEP) with laparoscopic Nissen fundoplication (LNF) in the treatment of uncomplicated reflux disease. *Am J Gastroenterol* 2006;101(3):431-436 (Mar)

Sgouros SN, Bergele C. Endoscopic therapy for gastroesophageal reflux disease: a systematic review. *Digestion* 2006;74(1):1-14 (Jan)

Rothstein RI, Dukowica AC. Endoscopic Therapy for Gastroesophageal Reflux Disease. *Surg Clin N Amer* 2005;85(5):949-965 (Oct)

Cappell MS. Clinical presentation, diagnosis, and management of gastroesophageal reflux disease. *Med Clin N Amer* 2005;89(2):243-291 (Mar)

DeVault KR, Castell DO. Updated guidelines for the Diagnosis and Treatment of Gastroesophageal Reflux Disease. *Am J Gastroenterol* 2005;100(1):190-200 (Jan)

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\*Consistent with Summary Plan Description (SPD). When there is discordance between this policy and the SPD, the provisions of the SPD prevail