

Medical Policy

Endoscopic Procedures or Magnetic Esophageal Sphincter Augmentation to Treat Gastrointestinal Reflux Disease (GERD) in the Outpatient Setting

Policy Number: OCA 3.46

Version Number: 22

Version Effective Date: 12/01/21

Product Applicability		<input checked="" type="checkbox"/> All Plan⁺ Products
WellSense Health Plan	Boston Medical Center HealthNet Plan	
<input checked="" type="checkbox"/> NH Medicaid	<input checked="" type="checkbox"/> MassHealth ACO	
<input checked="" type="checkbox"/> NH Medicare Advantage	<input checked="" type="checkbox"/> MassHealth MCO	
	<input checked="" type="checkbox"/> Qualified Health Plans/ConnectorCare/Employer Choice Direct	
	<input checked="" type="checkbox"/> Senior Care Options	

+ Note: Disclaimer and audit information is located at the end of this document.

Policy Summary

The Plan considers endoscopic treatments/transesophageal endoscopic therapies experimental and investigational or NOT medically necessary for the treatment of gastroesophageal reflux disease (GERD). The Plan considers the use of magnetic esophageal sphincter augmentation with the LINX Reflux Management System (implanted via laparoscope) to be experimental and investigational or NOT medically necessary as an alternative to laparoscopic fundoplication for members with medically intractable symptoms of GERD or for any other indication. Prior authorization is required.

It will be determined during the Plan’s prior authorization review process if the service is considered experimental and investigational for the requested indication. The Plan’s *Experimental and Investigational Treatment* medical policy, policy number OCA 3.12, specifies the product-specific

Endoscopic Procedures or Magnetic Esophageal Sphincter Augmentation to Treat Gastrointestinal Reflux Disease (GERD) in the Outpatient Setting

⁺ Plan refers to Boston Medical Center Health Plan, Inc. and its affiliates and subsidiaries offering health coverage plans to enrolled members. The Plan operates in Massachusetts under the trade name Boston Medical Center HealthNet Plan and in other states under the trade name WellSense New Hampshire Health Plan.

definitions of experimental or investigational treatment, and the Plan's *Medically Necessary* medical policy, policy number OCA 3.14, indicates the product-specific definitions of medically necessary treatment.

Clinical Criteria

1. The Plan considers the use of magnetic esophageal sphincter augmentation for the treatment of GERD experimental and investigational or NOT medically necessary as an alternative to laparoscopic fundoplication for members with partial response to pharmacotherapy or for any other indication due to the low-quality and limited evidence documenting the long-term efficacy and safety of the treatment.
2. The Plan considers endoscopic treatments/transesophageal endoscopic therapies experimental and investigational or NOT medically necessary for the treatment of GERD due to limited evidence demonstrating the clinical utility and clinical validity for this indication, including but not limited to endoscopic submucosal implantation/endoscopic injection of bulking agents, transesophageal radiofrequency (also known as the Stretta procedure), and/or endoscopic suturing/stapling/fastening/plication techniques (e.g., Bard® EndoCinch™ Suturing System, Plicator®/Endoscopic Plicator System).
3. The Plan considers transoral incisionless fundoplication (TIF) for the treatment of GERD to be experimental and investigational or NOT medically necessary based on the type of device and indication for treatment. Clinical alternatives to TIF for the treatment of GERD are laparoscopic Nissen fundoplication, laparoscopic Toupet fundoplication, the continued use of proton pump inhibitors (PPIs), or behavioral modification. Laparoscopic Nissen fundoplication (rather than endoscopic procedures including TIF) remains the gold standard in surgical interventions for GERD in both adults and children if conservative medical management fails or for those who suffer from complications. TIF can be performed using the EsophyX® device or the Medigus Ultrasonic Surgical Endostapler (MUSE™ system), as stated below in item a and item b:
 - a. Medigus Ultrasonic Surgical Endostapler (MUSE™ System, Medigus Ltd.):

The Plan considers TIF with the Medigus Ultrasonic Surgical Endostapler (MUSE™ system) to be experimental and investigational or NOT medically necessary when used for the treatment of GERD or for ANY other indication (including but not limited to grade A-B esophagitis and/or symptomatic chronic GERD) because of the inconsistent and limited evidence demonstrating favorable long-term outcomes as an alternative treatment strategy to established interventions considered the standard of care. Clinical alternatives to TIF MUSE™ include laparoscopic Nissen fundoplication, laparoscopic Toupet fundoplication, the continued use of proton pump inhibitors (PPIs), or behavioral modification.

Endoscopic Procedures or Magnetic Esophageal Sphincter Augmentation to Treat Gastrointestinal Reflux Disease (GERD) in the Outpatient Setting

* Plan refers to Boston Medical Center Health Plan, Inc. and its affiliates and subsidiaries offering health coverage plans to enrolled members. The Plan operates in Massachusetts under the trade name Boston Medical Center HealthNet Plan and in other states under the trade name WellSense New Hampshire Health Plan.

b. EsophyX® Device (EndoGastric Solutions, Inc.):

The Plan considers TIF with the EsophyX® device to NOT be medically necessary when used for the treatment of GERD due to inconsistent and limited evidence demonstrating favorable long-term outcomes as an alternative treatment strategy to established interventions considered the standard of care for GERD. The Plan considers TIF with the EsophyX® device experimental and investigational or NOT medically necessary when used for ANY other indication (e.g., grade A-B esophagitis) due to limited evidence demonstrating the clinical utility and clinical validity of this service. According to clinical guidelines published in 2017 by the Society of American Gastrointestinal and Endoscopic Surgeons (SAGES), TIF with an EsophyX® device can be performed with an acceptable safety risk in appropriately selected patients but appears to lose effectiveness during longer term follow-up. The National Institute for Health and Care Excellence (NICE) guidance 404 states that patients and providers must understand the uncertainty about the efficacy of antireflux endoluminal procedures, particularly in the long term.

Plan Medical Director review and final approval are required for all requests for TIF with the EsophyX® device when used for the treatment of GERD and it is a covered service for the member. **TIF for the treatment of GERD is a benefit exclusion for WellSense New Hampshire Medicaid members and therefore is NOT a covered service.** When TIF is a covered service for the Plan member, individual consideration will be conducted by the Plan Medical Director based on the guidelines outlined in the *Clinical Review Criteria* administrative policy, policy number OCA 3.201. The treating provider must submit medical record documentation with ALL of the information listed below in items (1) through (7):

- (1) Member has a diagnosis of GERD confirmed by either ambulatory esophageal pH monitoring, esophagram (barium swallow), or upper endoscopy; AND
- (2) Member's has a documented history of daily symptoms of severe GERD for at least 12 consecutive calendar months; AND
- (3) Member is 18 years of age or older on the date of service; AND
- (4) Member is a good candidate for the procedure and the EsophyX® device will be utilized according to Food and Drug Administration (FDA) approved indications; AND
- (5) Member has failed conservative treatment for severe GERD for at least six (6) consecutive calendar months that include ALL of the following documented interventions: lifestyle modification, weight loss (when applicable), and daily proton pump inhibitor use; AND

Endoscopic Procedures or Magnetic Esophageal Sphincter Augmentation to Treat Gastrointestinal Reflux Disease (GERD) in the Outpatient Setting

* Plan refers to Boston Medical Center Health Plan, Inc. and its affiliates and subsidiaries offering health coverage plans to enrolled members. The Plan operates in Massachusetts under the trade name Boston Medical Center HealthNet Plan and in other states under the trade name WellSense New Hampshire Health Plan.

- (6) Clinical documentation supports the use of TIF with EsophyX® as a medically necessary and preferred alternative intervention (both as short-term and long-term treatment) to laparoscopic Nissen fundoplication (the gold standard in surgical interventions for GERD) for the management of the member's condition; AND
- (7) Member does NOT have a contraindication for EsophyX® according to FDA labeling that includes ANY of the conditions listed in items (a) through (q):
- (a) Achalasia; OR
 - (b) Active gastro-duodenal ulcer disease (peptic ulcer); OR
 - (c) Barrett's esophagus > 2 cm
 - (d) Bleeding disorder; OR
 - (e) Body mass index (BMI) > 35; OR
 - (f) Chronic cough; OR
 - (g) Esophageal diverticulae; OR
 - (h) Esophageal infections or fungal disease; OR
 - (i) Esophageal stenosis; OR
 - (j) Esophagitis grade C or D; OR
 - (k) Esophageal stricture or narrowing; OR
 - (l) Esophageal varices; OR
 - (m) Gastric outlet obstruction or stenosis; OR
 - (n) Gastroparesis; OR
 - (o) Hiatal hernia > 2 cm in size; OR
 - (p) Limited neck mobility; OR
 - (q) Non-healing esophageal ulcer; OR

Endoscopic Procedures or Magnetic Esophageal Sphincter Augmentation to Treat Gastrointestinal Reflux Disease (GERD) in the Outpatient Setting

* Plan refers to Boston Medical Center Health Plan, Inc. and its affiliates and subsidiaries offering health coverage plans to enrolled members. The Plan operates in Massachusetts under the trade name Boston Medical Center HealthNet Plan and in other states under the trade name WellSense New Hampshire Health Plan.

- (r) Normal or abnormal esophageal anatomy, which would prohibit insertion of the device; OR
- (s) Inability to adhere to the postoperative diet recommended for appropriate healing; OR
- (t) Obstruction; OR
- (u) Osteophytes of the spine; OR
- (v) Paraesophageal hernia; OR
- (w) Portal hypertension and/or varices; OR
- (x) Pregnancy; OR
- (y) Prior esophageal surgery; OR
- (z) Scleroderma; OR
- (aa) Severe esophagitis; OR
- (bb) Suspected or confirmed esophageal or gastric cancer.

Limitations and Exclusions

See the Clinical Criteria section.

Variations

The Plan uses guidance from the Centers for Medicare & Medicaid Services (CMS) for medical necessity and coverage determinations for Senior Care Options (SCO) members and WellSense Medicare Advantage HOM members, including but not limited to national coverage determinations (NCCDs), local coverage determinations (LCDs), local coverage articles (LCAs), and documentation included in Medicare manuals. At the time of the Plan's most recent policy review, NCD 100.2, NCD 100.4 and LCD L35080 include medically necessary indications for endoscopic procedures for GERD. Verify CMS criteria in effect for the requested service on the date of the prior authorization request for a SCO or WellSense Medicare Advantage HMO member. When there is no guidance from CMS for the requested service for the specified indication on the date of the prior authorization request, Plan-adopted clinical review criteria will be used to determine the medical necessity of the service.

Endoscopic Procedures or Magnetic Esophageal Sphincter Augmentation to Treat Gastrointestinal Reflux Disease (GERD) in the Outpatient Setting

* Plan refers to Boston Medical Center Health Plan, Inc. and its affiliates and subsidiaries offering health coverage plans to enrolled members. The Plan operates in Massachusetts under the trade name Boston Medical Center HealthNet Plan and in other states under the trade name WellSense New Hampshire Health Plan.

Applicable Coding

The Plan uses and adopts up-to-date Current Procedural Terminology (CPT) codes from the American Medical Association (AMA), International Statistical Classification of Diseases and Related Health Problems, 10th revision (ICD-10) diagnosis codes developed by the World Health Organization and adapted in the United States by the National Center for Health Statistics (NCHS) of the Centers for Disease Control under the U.S. Department of Health and Human Services, and the Health Care Common Procedure Coding System (HCPCS) established and maintained by the Centers for Medicare & Medicaid Services (CMS). Since the AMA, NCHS, and CMS may update codes more frequently or at different intervals than Plan policy updates, the list of applicable codes included in this Plan policy is for informational purposes only, may not be all inclusive, and is subject to change without prior notification. Whether a code is listed in the Applicable Coding section of this Plan policy does not constitute or imply member coverage or provider reimbursement. Providers are responsible for reporting all services using the most up-to-date industry-standard procedure and diagnosis codes as published by the AMA, NCHS, and CMS at the time of the service.

Providers are responsible for obtaining prior authorization for the services specified in the Clinical Criteria and Limitations and Exclusions section, even if an applicable code appropriately describing the service that is the subject of this Plan policy is not included in the Applicable Coding section of this Plan policy. Review the Plan's reimbursement policies for Plan billing guidelines. Coverage for services is subject to benefit eligibility under the member's benefit plan in effect at the time of the service. Member benefit documents are available at the following websites: www.bmchp.org for BMC HealthNet Plan members, www.SeniorsGetMore.org for Senior Care Options members, www.wellsense.org for WellSense New Hampshire Medicaid members, and www.WellSense.org/Medicare for WellSense Medicare Advantage HMO members.

ICD-10 Diagnosis Codes	Description: Diagnosis Codes for Gastroesophageal Reflux Disease (GERD) Plan note: The Plan considers endoscopic treatments for the treatment of GERD to be experimental and investigational or NOT medically necessary.
K21.0 – K21.9	Gastroesophageal reflux disease
R12	Heartburn
CPT Codes	Description: Services Considered Experimental and Investigational or NOT Medically Necessary for the Treatment of GERD
43192	Esophagoscopy, rigid, transoral; with directed submucosal injection(s), any substance
43201	Esophagoscopy, flexible, transoral; with directed submucosal injection(s), any substance
43211	Esophagoscopy, flexible, transoral; with endoscopic mucosal resection
43212	Esophagoscopy, flexible, transoral; with placement of endoscopic stent (includes pre and post-dilation and guide wire passage, when performed)
43236	Esophagogastroduodenoscopy, flexible, transoral; with directed submucosal

Endoscopic Procedures or Magnetic Esophageal Sphincter Augmentation to Treat Gastrointestinal Reflux Disease (GERD) in the Outpatient Setting

* Plan refers to Boston Medical Center Health Plan, Inc. and its affiliates and subsidiaries offering health coverage plans to enrolled members. The Plan operates in Massachusetts under the trade name Boston Medical Center HealthNet Plan and in other states under the trade name WellSense New Hampshire Health Plan.

	injection(s), any substance
43254	Esophagogastroduodenoscopy, flexible, transoral; with endoscopic mucosal resection. Plan note: Code used for endoscopic banding and resection with the Duette Multi-Band Mucosectomy Device.
43257	Esophagogastroduodenoscopy, flexible, transoral; with delivery of thermal energy to the muscle of lower esophageal sphincter and/or gastric cardia, for treatment of gastroesophageal reflux disease
43284	Laparoscopy, surgical, esophageal sphincter augmentation procedure, placement of sphincter augmentation device (i.e., magnetic band), including cruroplasty when performed Plan note: Code used for magnetic esophageal sphincter augmentation with the LINX Reflux Management System (implanted via laparoscope) for the treatment of GERD. This code must be billed with an ICD-10 diagnosis for GERD, as specified above.

CPT Code	Description: Code Considered Either Experimental and Investigational or NOT Medically Necessary for the Treatment of GERD or Any Other Indication
43210	Esophagogastroduodenoscopy, flexible, transoral; with esophagogastric fundoplasty, partial or complete, includes duodenoscopy when performed Plan note: Code used for the transoral incisionless fundoplication (TIF) procedure.

References

American College of Gastroenterology (ACG). Patient Information. Endoscopic treatment of gastroesophageal reflux disease.

American College of Gastroenterology (ACG). Clinical Guidelines

American College of Gastroenterology (ACG). Katz PO, Gerson LB, Vela MF. Clinical Guidelines. Diagnosis and Management of Gastroesophageal Reflux Disease. Am J Gastroenterol. 2013 Mar;108(3):308 –28. doi: 10.1038/ajg.2012.444.

American Gastroenterological Association (AGA). Clinical Guidelines.

American Gastroenterological Association (AGA). Kahrilas PJ, Shaheen NJ, Vaezi MF, Hiltz SW, Black E, Modlin IM, Johnson SP, Allen J, Brill JV; AGA. AGA Medical Position Statements. Gastroesophageal Reflux Disease. Gastroenterology. 2008 Oct;135(4):1383-91.e5. doi: 10.1053/j.gastro.2008.08.045. PMID: 18789939.

Endoscopic Procedures or Magnetic Esophageal Sphincter Augmentation to Treat Gastrointestinal Reflux Disease (GERD) in the Outpatient Setting

* Plan refers to Boston Medical Center Health Plan, Inc. and its affiliates and subsidiaries offering health coverage plans to enrolled members. The Plan operates in Massachusetts under the trade name Boston Medical Center HealthNet Plan and in other states under the trade name WellSense New Hampshire Health Plan.

American Gastroenterological Association (AGA). Richter JE, Kumar A, Lipka S, Miladinovic B, Velanovich V. Efficacy of Laparoscopic Nissen Fundoplication vs Transoral Incisionless Fundoplication or Proton Pump Inhibitors in Patients With Gastroesophageal Reflux Disease: A Systematic Review and Network Meta-analysis. *Gastroenterology*. 2018 Apr;154(5):1298-1308.e7. doi: 10.1053/j.gastro.2017.12.021. Epub 2018 Jan 3. PMID: 29305934.

American Gastroenterological Association (AGA). Yadlapati R, Vaezi MF, Vela MF, Spechler SJ, Shaheen NJ, Richter J, Lacy BE, Katzka D, Katz PO, Kahrilas PJ, Gyawali PC, Gerson L, Fass R, Castell DO, Craft J, Hillman L, Pandolfino JE. Management options for patients with GERD and persistent symptoms on proton pump inhibitors: recommendations from an expert panel. *Am J Gastroenterol*. 2018 Jul;113(7):980-986. doi: 10.1038/s41395-018-0045-4. Epub 2018 Apr 24. doi: 10.1038/s41395-018-0045-4. PMID: 29686276.

American Society for Gastrointestinal Endoscopy (ASGE). Guidelines.

American Society for Gastrointestinal Endoscopy (ASGE). Muthusamy VR, Lightdale JR, Acosta RD, Chandrasekhara V, Chathad KV, Eloubeidi MA, Fanelli RD, Fonkalsrud A, Faulx AL, Khashab MA, Saltzman JR, Shaukat A, Wang A, Cash B, DeWitt JM; ASGE Standards of Practice Committee. Guideline: The role of endoscopy in the management of GERD. *Gastrointestinal Endoscopy*. 2015 Jun;81(6):1305-10. doi: 10.1016/j.gie.2015.02.021.

American Society of General Surgeons (ASGS). ASGS Position Statement Transoral Fundoplication.

American Society of General Surgeons (ASGS). LINX Statement of Support from ASGS. 2014

American Society of General Surgeons (ASGS). Nicastrì G. Position Statement. Coverage of Transoral Fundoplication. 2011 Apr 1.

American Society of General Surgeons (ASGS). Position Statements.

American Society of General Surgeons (ASGS). Position Statement. Natural Orifice Surgery and Transoral Incisionless Fundoplication. 2009.

Arts J, Bisschops R, Blondeau K, Farré R, Vos R, Holvoet L, Caenepeel P, Lerut A, Tack J. A double-blind sham-controlled study of the effect of radiofrequency energy on symptoms and distensibility of the gastro-esophageal junction in GERD. *Am J Gastroenterol*. 2012 Feb;107(2):222-30. doi: 10.1038/ajg.2011.395. Epub 2011 Nov 22. PMID: 22108449.

Endoscopic Procedures or Magnetic Esophageal Sphincter Augmentation to Treat Gastrointestinal Reflux Disease (GERD) in the Outpatient Setting

* Plan refers to Boston Medical Center Health Plan, Inc. and its affiliates and subsidiaries offering health coverage plans to enrolled members. The Plan operates in Massachusetts under the trade name Boston Medical Center HealthNet Plan and in other states under the trade name WellSense New Hampshire Health Plan.

Ashfaq A, Rhee HK, Harold KL. Revision of failed transoral incisionless fundoplication by subsequent laparoscopic Nissen fundoplication. *World J Gastroenterol*. 2014 Dec 7;20(45):17115–9. doi: 10.3748/wjg.v20.i45.17115. PMID: 25493024.

Asti E, Bonitta G, Lovece A, Lazzari V, Bonavina L. Longitudinal comparison of quality of life in patients undergoing laparoscopic Toupet fundoplication versus magnetic sphincter augmentation: Observational cohort study with propensity score analysis. *Medicine (Baltimore)*. 2016 Jul;95(30):e4366. doi: 10.1097/MD.0000000000004366. PMID: 27472725.

Aziz AM, El-Khayat HR, Sadek A, Mattar SG, McNulty G, Kongkam P, Guda MF, Lehman GA. A prospective randomized trial of sham, single-dose Stretta, and double-dose Stretta for the treatment of gastroesophageal reflux disease. *Surg Endosc*. 2010 Apr;24(4):818-25. doi: 10.1007/s00464-009-0671-4. PMID: 19730952.

Barnes WE, Hoddinott KM, Mundy S, Williams M. Transoral incisionless fundoplication offers high patient satisfaction and relief of therapy-resistant typical and atypical symptoms of GERD in community practice. *Surgical Innov*. 2011 Jun;18(2):119-29. doi: 10.1177/1553350610392067. Epub 2011 Feb 8. PMID: 21307014.

Bell RC, Freeman KD. Clinical and pH-metric outcomes of transoral esophagogastric fundoplication for the treatment of gastroesophageal reflux disease. *Surg Endosc*. 2011 Jun;25(6):1975–84. doi: 10.1007/s00464-010-1497-9. PMID: 21140170.

Bell RC, Barnes WE, Carter BJ, Sewell RW, Mavrelis PG, Ihde GM, Hoddinott KM, Fox MA, Freeman KD, Gunsberger T, Hausmann MG, Dargis D, DaCosta Gill B, Wilson E, Trad KS. Transoral incisionless fundoplication: 2-year results from the prospective multicenter U.S. study. *Am Surg*. 2014 Nov;80(11):1093-105. PMID: 25347499.

Bell RC, Fox MA, Barnes WE, Mavrelis PG, Sewell RW, Carter BJ, Ihde GM, Trad KS, Dargis D, Hoddinott KM, Freeman KD, Gunsberger T, Hausmann MG, Gill BD, Wilson E. Univariate and multivariate analyses of preoperative factors influencing symptomatic outcomes of transoral fundoplication. *Surg Endosc*. 2014 Oct;28(10):2949-58. doi: 10.1007/s00464-014-3557-z. Epub 2014 May 31. PMID: 24879134.

Bell RC, Mavrelis PG, Barnes WE, Dargis D, Carter BJ, Hoddinott KM, Sewell RW, Trad KS, DaCosta Gill B, Ihde GM. A prospective multicenter registry of patients with chronic gastroesophageal reflux disease receiving transoral incisionless fundoplication. *J Am Coll Surg*. 2012 Dec;215(6):794-809. doi: 10.1016/j.jamcollsurg.2012.07.014. Epub 2012 Aug 29. PMID: 22939637.

Birk J, Pruitt R, Haber G, Rajman I, Baluyut A, Meiselman M, Sedghi S. The Plicator procedure for the treatment of gastroesophageal reflux disease: a registry study. *Surg Endosc*. 2009 Feb;23(2):423-31. doi: 10.1007/s00464-008-0109-4. Epub 2008 Sep 24. PMID: 18814008.

Endoscopic Procedures or Magnetic Esophageal Sphincter Augmentation to Treat Gastrointestinal Reflux Disease (GERD) in the Outpatient Setting

* Plan refers to Boston Medical Center Health Plan, Inc. and its affiliates and subsidiaries offering health coverage plans to enrolled members. The Plan operates in Massachusetts under the trade name Boston Medical Center HealthNet Plan and in other states under the trade name WellSense New Hampshire Health Plan.

Bonavina L, DeMeester T, Fockens P, et al. Laparoscopic sphincter augmentation device eliminates reflux symptoms and normalizes esophageal acid exposure: one- and 2-year results of a feasibility trial. *Ann Surg*. 2010 Nov;252(5):857-62. doi: 10.1097/SLA.0b013e3181fd879b. PMID: 21037442.

Bredenoord AJ, Pandolfino JE, Smout AJ. Gastro-esophageal reflux disease. *Lancet*. 2013 Jun 1;381(9881):1933-42. doi: 10.1016/S0140-6736(12)62171-0. Epub 2013 Mar 8. PMID: 23477993.

Cadière GB, Buset M, Muls V, Rajan A, Rösch T, Eckardt A, Weerts J, Bastens B, Costamagna G, Marchese M, Louis H, Mana F, Sermon F, Gawlicka AK, Daniel MA, Devière J. Antireflux transoral incisionless fundoplication using EsophyX: 12-month results of a prospective multicenter study. *World J Surg*. 2008 August;32(8):1676–88. doi: 10.1007/s00268-008-9594-9. PMID: 18443855.

Cadière GB, Rajan A, Germay O, Himpens J. Endoluminal fundoplication by a transoral device for the treatment of GERD: A feasibility study. *Surg Endosc*. 2008 Feb;22(2):333-42. Epub 2007 Dec 11. doi: 10.1007/s00464-007-9618-9. PMID: 18071818.

Cadière GB, Van Sante N, Graves JE, Gawlicka AK, Rajan A. Two-year results of a feasibility study on antireflux transoral incisionless fundoplication (TIF) using EsophyX. *Surg Endosc*. 2009 May;23(5):957–64. doi: 10.1007/s00464-009-0384-8. Epub 2009 Mar 14. PMID: 19288158.

Campos GM, Vittinghoff E, Rabl C, Takata M, Gadenstätter M, Lin F, Ciovica R. Endoscopic and surgical treatments for achalasia: a systematic review and meta-analysis. *Ann Surg*. 2009 Jan;249(1):45-57. doi: 10.1097/SLA.0b013e3181818e43ab. PMID: 19106675.

Centers for Medicare & Medicaid Services (CMS). Local Coverage Determination (LCD) for Select Minimally Invasive GERD Procedures. L35080. National Government Services. 2015 Oct 1. Updated 2021 Apr 15.

Centers for Medicare & Medicaid Services (CMS). Manuals. Publication # 100-02. Medicare Benefit Policy Manual.

Centers for Medicare and Medicaid Services (CMS). Manuals. Publication # 100-03. Medicare National Coverage Determinations (NCD) Manual

Centers for Medicare & Medicaid Services (CMS). Medicare Coverage Database (MCD). Welcome to the MCD Search.

Centers for Medicare & Medicaid Services (CMS). National Coverage Determination (NCD) for Endoscopy. 100.2. Effective date not posted.

Endoscopic Procedures or Magnetic Esophageal Sphincter Augmentation to Treat Gastrointestinal Reflux Disease (GERD) in the Outpatient Setting

* Plan refers to Boston Medical Center Health Plan, Inc. and its affiliates and subsidiaries offering health coverage plans to enrolled members. The Plan operates in Massachusetts under the trade name Boston Medical Center HealthNet Plan and in other states under the trade name WellSense New Hampshire Health Plan.

Centers for Medicare & Medicaid Services (CMS). National Coverage Determination (NCD) for Esophageal Manometry. 100.4. 1978 Oct 2.

Centers for Medicare & Medicaid Services (CMS). National Coverage Determination (NCD) for Implantation of Anti-Gastroesophageal Reflux Device. 100.9. 1987 Jun 22.

Chao K, Chuah SK. Antireflux Endoluminal Therapies: Past and Present. *Gastroenterol Res Pract*. 2013;2013:481417. Published online 2013 Jul 9. doi: 10.1155/2013/481417. PMID: 23935608.

Chen MY, Huang DY, Wu A, Zhu YB, Zhu HP, Lin LM, Cai XJ. Efficacy of magnetic sphincter augmentation versus Nissen fundoplication for gastroesophageal reflux disease in short term: a meta-analysis. *Can J Gastroenterol Hepatol*. 2017;2017:9596342.

Commonwealth of Massachusetts. Division of Insurance (DOI) Bulletins.

Commonwealth of Massachusetts. MassHealth Provider Bulletins.

Commonwealth of Massachusetts. MassHealth Provider Manuals.

Commonwealth of Massachusetts. MassHealth Transmittal Letters.

Danalioglu A, Cipe G, Toydemir T, Kocaman O, Ince AT, Muslumanoglu M, Senturk H. Endoscopic stapling in comparison to laparoscopic fundoplication for the treatment of gastroesophageal reflux disease. *Dig Endosc*. 2014 Jan;26(1):37-42. doi: 10.1111/den.12081. Epub 2013 Apr 7. PMID: 23560891.

Das B, Reddy M, Khan OA. Is the Stretta procedure as effective as the best medical and surgical treatments for gastro-esophageal reflux disease? A best evidence topic. *Int J Surg*. 2016 Jun;30:19-24. doi: 10.1016/j.ijvsu.2016.03.062. Epub 2016 Apr 5. PMID: 27058112.

Demyttenaere SV, Bergman S, Pham T, Anderson J, Dettorre R, Melvin WS, Mikami DJ. Transoral incisionless fundoplication for gastroesophageal reflux disease in an unselected patient population. *Surg Endosc*. 2010 Apr;24(4):854-8. doi: 10.1007/s00464-009-0676-z. PMID: 19730949.

Dughera L, Rotondano G, De Cento M, Cassolino P, Cisarò F. Durability of Stretta Radiofrequency Treatment for GERD: Results of an 8-Year Follow-Up. *Gastroenterol Res Pract*. 2014;2014:531907. doi: 10.1155/2014/531907. Epub 2014 May 18. PMID: 24959175.

EndoGastric Solutions. EsophyX® Device

EndoGastric Solutions. TIF Procedure Reimbursement.

Endoscopic Procedures or Magnetic Esophageal Sphincter Augmentation to Treat Gastrointestinal Reflux Disease (GERD) in the Outpatient Setting

* Plan refers to Boston Medical Center Health Plan, Inc. and its affiliates and subsidiaries offering health coverage plans to enrolled members. The Plan operates in Massachusetts under the trade name Boston Medical Center HealthNet Plan and in other states under the trade name WellSense New Hampshire Health Plan.

European Association of Endoscopic Surgery (EAES). Fuchs KH, Babic B, Breithaupt W, Dallemagne B, Fingerhut A, Furnee E, Granderath F, Horvath P, Kardos P, Pointner R, Savarino E, Van Herwaarden-Lindeboom M, Zaninotto G; EAES. EAES recommendations for the management of gastroesophageal reflux disease. *Surg Endosc.* 2014 Jun;28(6):1753-73. doi: 10.1007/s00464-014-3431-z. Epub 2014 May 2. PMID: 24789125.

Fass R. An Overview of Transoral Incisionless Fundoplication and Magnetic Sphincter Augmentation for GERD. *Gastroenterol Hepatol (N Y).* 2017 Jan;13(1):50-52. PMID: 28420946.

Fockens P, Cohen L, Edmundowicz SA, Binmoeller K, Rothstein RI, Smith D, Lin E, Nickl N, Overholt B, Kahrilas PJ, Vakil N, Abdel-Aziz Hassan AM, Lehman GA. Prospective randomized controlled trial of an injectable esophageal prosthesis versus a sham procedure for endoscopic treatment of gastroesophageal reflux disease. *Surg Endosc.* 2010 Jun;24(6):1387-97. doi: 10.1007/s00464-009-0784-9. Epub 2010 Mar 3. PMID: 20198491.

Funk LM, Zhang JY, Drosdeck JM, Melvin WS, Walker JP, Perry KA. Long-term cost-effectiveness of medical, endoscopic and surgical management of gastroesophageal reflux disease. *Surgery.* 2015 Jan;157(1):126-36. doi: 10.1016/j.surg.2014.05.027. Epub 2014 Sep 26. PMID: 25262216.

Gawron AJ, French DD, Pandolfino JE, Howden CW. Economic evaluations of gastroesophageal reflux disease medical management. *Pharmacoeconomics.* 2014 Aug;32(8):745-58. doi: 10.1007/s40273-014-0164-8. PMID: 24807469.

Håkansson B, Montgomery M, Cadiere GB, Rajan A, Bruley des Varannes S, Lerhun M, Coron E, Tack J, Bischops R, Thorell A, Arnelo U, Lundell L. Randomised clinical trial: transoral incisionless fundoplication vs. sham intervention to control chronic GERD. *Aliment Pharmacol Ther.* 2015 Dec;42(11-12):1261-70. doi: 10.1111/apt.13427. Epub 2015 Oct 13. PMID: 26463242.

Hayes. Clinical Research Response. EsophyX Device (Endogastric Solutions) Versus LINX Reflux Management System (Ethicon). Product Comparison. Dallas, TX: Hayes 2021 Jun 25.

Hayes. Comparative Effectiveness Review. Comparative Effectiveness Review of Endoscopic Therapy for Gastroesophageal Reflux Disease. Dallas, TX: Hayes; 2017 Dec 7. Annual Review 2021 Feb 24.

Hayes. Health Technology Assessment. Magnetic Sphincter Augmentation (LINX Reflux Management System) for Treatment of Gastroesophageal Reflux Disease. Dallas, TX: Hayes; 2018 Dec 6. Updated 2021 Feb 3.

Herregods TV, Bredenoord AJ, Smout AJ. Pathophysiology of gastroesophageal reflux disease: new understanding in a new era. *Neurogastroenterol Motil.* 2015 Sep;27(9):1202-13. doi: 10.1111/nmo.12611. Epub 2015 Jun 5. PMID: 26053301.

Endoscopic Procedures or Magnetic Esophageal Sphincter Augmentation to Treat Gastrointestinal Reflux Disease (GERD) in the Outpatient Setting

* Plan refers to Boston Medical Center Health Plan, Inc. and its affiliates and subsidiaries offering health coverage plans to enrolled members. The Plan operates in Massachusetts under the trade name Boston Medical Center HealthNet Plan and in other states under the trade name WellSense New Hampshire Health Plan.

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

Huang X, Chen S, Zhao H, Zeng X, Lian J, Tseng Y, Chen J. Efficacy of transoral incisionless fundoplication (TIF) for the treatment of GERD: a systematic review with meta-analysis. *Surg Endosc*. 2017 Mar;31(3):1032-44. doi: 10.1007/s00464-016-5111-7. Epub 2016 Aug 5. PMID: 27495332.

Hunter JG, Kahrilas PJ, Bell RC, Wilson EB, Trad KS, Dolan JP, Perry KA, Oelschlager BK, Soper NJ, Snyder BE, Burch MA, Melvin WS, Reavis KM, Turgeon DG, Hungness ES, Diggs BS. Efficacy of transoral fundoplication vs omeprazole for treatment of regurgitation in a randomized controlled trial. *Gastroenterology*. 2015 Feb;148(2):324-33.e5. doi: 10.1053/j.gastro.2014.10.009. Epub 2014 Oct 13. PMID: 25448925.

International Pediatric Endosurgery Group (IPEG). Guidelines.

International Pediatric Endosurgery Group (IPEG). IPEG Guidelines for the Surgical Treatment of Pediatric Gastroesophageal Reflux Disease (GERD). *J Laparoendosc Adv Surg Tech A*. 2009 Apr;19 Suppl 1: x-xiii. doi: 10.1089/lap.2009.9982.suppl. PMID: 19371153.

Kahrilas PJ. Clinical manifestations and diagnosis of gastroesophageal reflux in adults. *UpToDate*. 2020 Jan 28.

Kaindlstorfer A, Koch OO, Antoniou SA, Asche KU, Granderath FA, Pointner R. A randomized trial on endoscopic full-thickness gastroplication versus laparoscopic antireflux surgery in GERD patients without hiatal hernias. *Surg Laparosc Endosc Percutan Tech*. 2013 Apr;23(2):212-22. doi: 10.1097/SLE.0b013e3182827f79. PMID: 23579521.

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 Aug;30(8):3402-8. doi: 10.1007/s00464-015-4622-y. Epub 2015 Nov 4. PMID: 26537905.

Kim WH, Park PW, Hahm KB, Hong SP. Endoscopic treatment of refractory gastroesophageal reflux disease. *Clin Endosc*. 2013 May;46(3):230-4. doi: 10.5946/ce.2013.46.3.230. Epub 2013 May 31. PMID: 23767031.

Liang WT, Yan C, Wang ZG, Wu JM, Hu ZW, Zhan XL, Wang F, Ma SS, Chen MP. Early and Midterm Outcome After Laparoscopic Fundoplication and a Minimally Invasive Endoscopic Procedure in Patients with Gastroesophageal Reflux Disease: A Prospective Observational Study. *J Laparoendosc Adv Surg Tech A*. 2015 Aug;25(8):657-61. doi: 10.1089/lap.2015.0188. PMID: 26258269.

Endoscopic Procedures or Magnetic Esophageal Sphincter Augmentation to Treat Gastrointestinal Reflux Disease (GERD) in the Outpatient Setting

* Plan refers to Boston Medical Center Health Plan, Inc. and its affiliates and subsidiaries offering health coverage plans to enrolled members. The Plan operates in Massachusetts under the trade name Boston Medical Center HealthNet Plan and in other states under the trade name WellSense New Hampshire Health Plan.

Lipham JC, Taiganides PA, Louie BE, Ganz RA, DeMeester TR. Safety analysis of first 1000 patients treated with magnetic sphincter augmentation for gastroesophageal reflux disease. *Dis Esophagus*. 2015;28(4):305-11.

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 Jun;13(6):1058-67.e1. doi: 10.1016/j.cgh.2014.10.013. Epub 2014 Oct 18. PMID: 25459556.

Mahmood Z, Ang YS. EndoCinch treatment for gastro-esophageal reflux disease. *Digestion*. 2007;76(3-4):241-7. doi: 10.1159/000112853. Epub 2008 Jan 4. PMID: 18176078.

Medigus Ltd. About the MUSE™ System.

Moore M, Afaneh C, Benhuri D, Antonacci C, Abelson J, Zarnegar R. Gastroesophageal reflux disease: A review of surgical decision making. *World J Gastrointest Surg*. 2016 Jan 27;8(1):77-83. doi: 10.4240/wjgs.v8.i1.77. PMID: 26843915.

Nabi Z, Reddy DN. Endoscopic Management of Gastroesophageal Reflux Disease: Revisited. *Clin Endosc*. 2016 Sep;49(5):408–16. doi: 10.5946/ce.2016.133. Epub 2016 Sep 30. PMID: 27744659.

National Institute for Health and Care Excellence (NICE). Endoluminal gastroplication for gastro-esophageal reflux disease. *Interventional Procedure Guidance IPG404*. 2011 Jul 27.

National Institute for Health and Care Excellence (NICE). Endoscopic injection of bulking agents for gastro-esophageal reflux disease. *Interventional Procedure Guidance IPG55*. 2004 Apr 28.

National Institute for Health and Care Excellence (NICE). Endoscopic radiofrequency ablation for gastro-oesophageal reflux disease. *Interventional Procedure Guidance IPG 461*. 2013 Aug 28.

National Institute for Health and Care Excellence (NICE). Gastro-esophageal reflux disease and dyspepsia in adults: investigation and management. *Clinical guideline CG184*. 2014 Sep 3.

National Institute for Health and Care Excellence (NICE). Laparoscopic insertion of a magnetic titanium ring for gastro-oesophageal reflux disease. *Interventional procedures guidance IPG 585*. 2017 Jul 26.

National Institutes of Health. National Heart, Lung, and Blood Institute. North American Association for the Study of Obesity. *The Practical Guide: Identification, Evaluation, and Treatment of Overweight and Obesity in Adults*. NIH Publication Number 00-4084. 2000 Oct.

New Hampshire Department of Health and Human Services. *Billing Manuals*.

Endoscopic Procedures or Magnetic Esophageal Sphincter Augmentation to Treat Gastrointestinal Reflux Disease (GERD) in the Outpatient Setting

* Plan refers to Boston Medical Center Health Plan, Inc. and its affiliates and subsidiaries offering health coverage plans to enrolled members. The Plan operates in Massachusetts under the trade name Boston Medical Center HealthNet Plan and in other states under the trade name WellSense New Hampshire Health Plan.

New Hampshire Department of Health and Human Services. Provider Notices.

North American Society for Pediatric Gastroenterology, Hepatology, and Nutrition (NASPGHAN) and European Society for Pediatric Gastroenterology, Hepatology, and Nutrition (ESPGHAN). Rosen R, Vandenplas Y, Singendonk M, Cabana M, DiLorenzo C, Gottrand F, Gupta S, Langendam M, Staiano A, Thapar N, Tipnis N, Tabbers M. Pediatric Gastroesophageal Reflux Clinical Practice Guidelines: Joint Recommendations of the NASPGHAN and ESPGHAN. *J Pediatr Gastroenterol Nutr*. 2018 Mar;66(3):516-44. doi: 10.1097/MPG.0000000000001889. PMID: 29470322.

Pandolfino JE, Krishnan K. Do endoscopic antireflux procedures fit in the current treatment paradigm of gastroesophageal reflux disease? *Clin Gastroenterol Hepatol*. 2014 Apr;12(4):544-54. doi: 10.1016/j.cgh.2013.06.012. Epub 2013 Jun 28. PMID: 23811248.

Rodrigues JP, Baldaque-Silva F. Once Upon a Time in the Esophagus. *Gastroenterology*. 2019 Mar;156(4):874-5. DOI: <https://doi.org/10.1053/j.gastro.2018.10.002>

Patti MG. Gastroesophageal Reflux Disease Treatment & Management. *Medscape*. 2019 May 23.

Reynolds JL, Zehetner J, Nieh A, et al. Charges, outcomes, and complications: a comparison of magnetic sphincter augmentation versus laparoscopic Nissen fundoplication for the treatment of GERD. *Surg Endosc*. 2016;30(8):3225-3230.

Schwartzberg SD. Surgical management of gastroesophageal reflux in adults. *UptoDate*. 2020 Feb 12.

Schwartz MP, Schreinemakers JRC, Smout AJPM. Four-year follow-up of endoscopic gastroplication for the treatment of gastroesophageal reflux disease. *World J Gastrointest Pharmacol Ther*. 2013 Nov 6;4(4):120–6. doi: 10.4292/wjgpt.v4.i4.120. PMID: 24199028.

Society of American Gastrointestinal and Endoscopic Surgeons (SAGES). Guidelines for Surgical Treatment of Gastroesophageal Reflux Disease (GERD). 2010 Feb.

Society of American Gastrointestinal and Endoscopic Surgeons (SAGES). Pearl J, Pauli E, Dunkin B, Stefanidis D. SAGES endoluminal treatments for GERD. *Surg Endosc*. 2017 Oct;31(10):3783-90. doi: 10.1007/s00464-017-5639-1. Epub 2017 Jun 22. PMID: 28643067.

Society of American Gastrointestinal and Endoscopic Surgeons (SAGES). Position Statement on Endoluminal Therapies for Gastrointestinal Diseases. 2009 Nov.

Society of American Gastrointestinal and Endoscopic Surgeons (SAGES). SAGES Clinical/Practice/Training Guidelines, Statements, and Standards of Practice.

Endoscopic Procedures or Magnetic Esophageal Sphincter Augmentation to Treat Gastrointestinal Reflux Disease (GERD) in the Outpatient Setting

* Plan refers to Boston Medical Center Health Plan, Inc. and its affiliates and subsidiaries offering health coverage plans to enrolled members. The Plan operates in Massachusetts under the trade name Boston Medical Center HealthNet Plan and in other states under the trade name WellSense New Hampshire Health Plan.

Society of American Gastrointestinal and Endoscopic Surgeons (SAGES). Stefanidis D, Richardson W, Dunkin B. Clinical Spotlight Review: Endolumenal Treatments for Gastroesophageal Reflux Disease (GERD). 2017 May.

Society of American Gastrointestinal and Endoscopic Surgeons (SAGES). Telem DA, Wright AS, Shah PC, Hutter MM. SAGES technology and value assessment committee (TAVAC) safety and effectiveness analysis: LINX(®) reflux management system. *Surg Endosc*. 2017;31(10):3811-26.

Stanak M, Erdos J, Hawlik K, Birsan T. Novel surgical treatments for gastroesophageal reflux disease: systematic review of magnetic sphincter augmentation and electric stimulation therapy. *Gastroenterology Res*. 2018;11(3):161-173.

Testoni PA, Mazzoleni G, Testoni SG. Transoral incisionless fundoplication for gastro-esophageal reflux disease: Techniques and outcomes. *World J Gastrointest Pharmacol Ther*. 2016 May 6;7(2):179–89. doi: 10.4292/wjgpt.v7.i2.179. PMID: 27158533.

Testoni PA, Vailati C, Testoni S, Corsetti M. Transoral incisionless fundoplication (TIF 2.0) with EsophyX for gastroesophageal reflux disease: long-term results and findings affecting outcome. *Surg Endosc*. 2012 May;26(5):1425-35. doi: 10.1007/s00464-011-2050-1. Epub 2011 Dec 15. PMID: 22170317.

Toomey P, Teta A, Patel K, Ross S, Sukharamwala P, Rosemurgy AS. Transoral incisionless fundoplication: is it as safe and efficacious as a Nissen or Toupet fundoplication? *Am Surg*. 2014 Sep;80(9):860-7. PMID: 25197871.

Trad KS, Barnes WE, Simoni G, Shughoury AB, Mavrelis PG, Raza M, Heise JA, Turgeon DG, Fox MA. Transoral incisionless fundoplication effective in eliminating GERD symptoms in partial responders to proton pump inhibitor therapy at 6 months: the TEMPO Randomized Clinical Trial. *Surg Innov*. 2015 Feb;22(1):26-40. doi: 10.1177/1553350614526788. Epub 2014 Apr 21. PMID: 24756976.

U. S. Food and Drug Administration (FDA). Medical Devices. 510(k) Clearances

U. S. Food and Drug Administration (FDA). Medical Devices. Device Registration and Listing.

U.S. Food and Drug Administration (FDA). Medical Devices. 510(k) Premarket Notification. 510(k) Summary. Bard® Endoscopic Suturing System. K994290. 2000 Mar 20.

U.S. Food and Drug Administration (FDA). Medical Devices. 510(k) Premarket Notification. 510(k) Summary. CSM Stretta™ System. K000245. 2000 Apr 18.

U.S. Food and Drug Administration (FDA). Medical Devices. 510(k) Premarket Notification. 510(k) Summary. NDO Surgical Endoscopic Plication System. K031262. 2003 May 23.

Endoscopic Procedures or Magnetic Esophageal Sphincter Augmentation to Treat Gastrointestinal Reflux Disease (GERD) in the Outpatient Setting

* Plan refers to Boston Medical Center Health Plan, Inc. and its affiliates and subsidiaries offering health coverage plans to enrolled members. The Plan operates in Massachusetts under the trade name Boston Medical Center HealthNet Plan and in other states under the trade name WellSense New Hampshire Health Plan.

U.S. Food and Drug Administration (FDA). Medical Devices. 510(k) Summary. EndoGastric Solutions (EGS) EsophyX™ System with SeraFuse™ Fastener and accessories. K071651. 2007 Sep 14.

U.S. Food and Drug Administration (FDA). Medical Devices. 510(k) Summary. EndoGastric Solutions (EGS) EsophyX2 HD Device with SeraFuse Fastener and Accessories, EsophyX Z Device with SerosaFuse Fasteners and Accessories. K171301. 2017 Jun 22

U.S. Food and Drug Administration (FDA). Medical Devices. 510(k) Summary. EndoGastric Solutions EsophyX2™ System. K092400. 2009 Jul 24.

U.S. Food and Drug Administration (FDA). Medical Devices. Class 2 Device Recall LINX Reflux Management System. 2018.

Devices. Premarket Approval (PMA). LINX Reflux Management System. 2010 Dec 30.

Wilson EB, Barnes WE, Mavrelis PG, Carter BJ, Bell RC, Sewell RW, Ihde GM, Dargis D, Hoddinott KM, Shughoury AB, Gill BD, Fox MA, Turgeon DG, Freeman KD, Gunsberger T, Hausmann MG, Leblanc KA, Deljkich E, Trad KS. The effects of transoral incisionless fundoplication on chronic GERD patients: 12-month prospective multicenter experience. *Surg Laparosc Endosc Percutan Tech*. 2014 Feb;24(1):36-46. doi: 10.1097/SLE.0b013e3182a2b05c. PMID: 24487156.

Witteman BP, Conchillo JM, Rinsma NF, Betzel B, Peeters A, Koek GH, Stassen LP, Bouvy ND. Randomized controlled trial of transoral incisionless fundoplication vs. proton pump inhibitors for treatment of gastroesophageal reflux disease. *Am J Gastroenterol*. 2015 Apr;110(4):531-42. doi: 10.1038/ajg.2015.28. Epub 2015 Mar 31. PMID: 25823768.

Yan C, Liang WT, Wang ZG, Hu ZW, Wu JM, Zhang C, Chen MP. Comparison of Stretta procedure and toupet fundoplication for gastroesophageal reflux disease-related extra-esophageal symptoms. *World J Gastroenterol*. 2015 Dec 7;21(45):12882-7. doi: 10.3748/wjg.v21.i45.12882. PMID: 26668513.

Yew KC, Chuah SK. Antireflux endoluminal therapies: past and present. *Gastroenterol Res Pract*. 2013;2013:481417. doi: 10.1155/2013/481417. Epub 2013 Jul 9. PMID: 23935608.

Zacherl J, Roy-Shapira A, Bonavina L, Bapaye A, Kiesslich R, Schoppmann SF, Kessler WR, Selzer DJ, Broderick RC, Lehman GA, Horgan S. Endoscopic anterior fundoplication with the Medigus Ultrasonic Surgical Endostapler (MUSE™) for gastroesophageal reflux disease: 6-month results from a multi-center prospective trial. *Surg Endosc*. 2015 Jan; 29(1):220-9. doi: 10.1007/s00464-014-3731-3. Epub 2014 Aug 19. PMID: 25135443.

Zhang H, Yang Z, Ni Z, Shi Y. A meta-analysis and systematic review of the efficacy of twice daily PPIs versus once daily for treatment of gastroesophageal reflux disease. *Gastroenterol Res Pract*. 2017;2017:9865963. doi: 10.1155/2017/9865963. Epub 2017 Aug 22. PMID: 28912807.

Endoscopic Procedures or Magnetic Esophageal Sphincter Augmentation to Treat Gastrointestinal Reflux Disease (GERD) in the Outpatient Setting

* Plan refers to Boston Medical Center Health Plan, Inc. and its affiliates and subsidiaries offering health coverage plans to enrolled members. The Plan operates in Massachusetts under the trade name Boston Medical Center HealthNet Plan and in other states under the trade name WellSense New Hampshire Health Plan.

Policy History

Original Approval Date	Original Effective Date* and Version Number	Policy Owner	Original Policy Approved by
Regulatory Approval: N/A Internal Approval: 08/01/06	10/01/06 Version 1	Director of Medical Policy as Chair of Medical Policy, Criteria, and Technology Assessment Committee (MPCTAC)	Quality and Clinical Management Committee (Q&CMC)

*Effective Date for the BMC HealthNet Plan Commercial Product: 01/01/12

*Effective Date for the WellSense New Hampshire Medicaid Product: 01/01/13

*Effective Date for the Senior Care Options Product: 01/01/16

*Effective Date for the WellSense Medicare Advantage HMO Product: 01/01/22

Policy formerly titled *Endoscopic Treatments for GERD in the Outpatient Setting* until 10/31/16. From 11/01/16 to 09/30/19 the policy title was *Endoscopic Treatments for GERD in the Outpatient Setting (Including Transoral Incisionless Fundoplication)*. From 10/01/19 to 10/01/20, the policy title was *Endoscopic Procedures for Gastrointestinal Reflux Disease (GERD) in the Outpatient Setting*. As of 10/01/20, the policy title is *Endoscopic Procedures or Magnetic Esophageal Sphincter Augmentation to Treat Gastrointestinal Reflux Disease (GERD) in the Outpatient Setting*.

Policy Revisions History

Review Date	Summary of Revisions	Revision Effective Date and Version Number	Approved by
07/11/07	Updated template and references. Added coding.	Version 2	07/11/07: MPCTAC 07/24/07: Utilization Management Committee (UMC) 08/13/07: QIC
07/08/08	Added additional devices and updated references.	Version 3	07/08/08: MPCTAC 07/22/08: UMC 08/13/08: QIC
07/28/09	Updated references.	Version 4	07/28/09: MPCTAC 07/28/09: UMC 08/26/09: QIC
06/01/10	Updated references and devices for application. No criteria changes.	Version 5	06/30/10: MPCTAC 07/28/10: QIC
07/01/11	Updated references.	Version 6	08/17/11: MPCTAC 09/28/11: QIC
07/29/12	Off cycle review for WellSense New	Version 7	08/03/12: MPCTAC

Endoscopic Procedures or Magnetic Esophageal Sphincter Augmentation to Treat Gastrointestinal Reflux Disease (GERD) in the Outpatient Setting

* Plan refers to Boston Medical Center Health Plan, Inc. and its affiliates and subsidiaries offering health coverage plans to enrolled members. The Plan operates in Massachusetts under the trade name Boston Medical Center HealthNet Plan and in other states under the trade name WellSense New Hampshire Health Plan.

Policy Revisions History

	Hampshire Product, revised Summary statement, revised Medical Policy Statement. Review of entire policy conducted.		09/05/12: QIC
10/01/12	Review for effective date 12/01/12. Revised Summary and Medical Policy Statement sections. Referenced <i>Experimental and Investigational Treatment</i> policy and <i>Transoral Incisionless Fundoplication (TIF) with the EsoPHYX System for Gastroesophageal Reflux Disease</i> medical policy. Updated language in introductory paragraph of Applicable Coding section and updated References section.	12/01/12 Version 8	10/17/12: MPCTAC 11/28/12: QIC
08/14/15 and 08/15/13	Off cycle review for WellSense New Hampshire Product and merged policy format. Incorporate policy revisions dated 10/01/12 (as specified above) for the WellSense New Hampshire Product; these policy revisions were approved by MPCTAC on 10/17/12 and QIC on 11/28/12 for applicable Plan products. Review of entire policy conducted.	Version 9	08/14/13: MPCTAC (electronic vote) 08/15/13: QIC
08/21/13	Review for effective date 10/01/13. Revised Summary and updated references.	10/01/13 Version 10	08/21/13: MPCTAC 09/19/13: QIC
09/01/14	Review for effective date 01/01/15. Updated Description of Item or Service, Clinical Background Information, and References sections. Added CPT code 43192 as an applicable code. Added ICD9 and ICD10 diagnosis codes for GERD, since the services specified in the applicable CPT codes are considered experimental and investigational when used for the treatment of GERD.	01/01/15 Version 11	09/17/14: MPCTAC 10/08/14: QIC
09/01/15	Review for effective date 11/01/15. Updated template, including the removal of Commonwealth Care,	11/01/15 Version 12	09/16/15: MPCTAC 10/14/15: QIC

Endoscopic Procedures or Magnetic Esophageal Sphincter Augmentation to Treat Gastrointestinal Reflux Disease (GERD) in the Outpatient Setting

* Plan refers to Boston Medical Center Health Plan, Inc. and its affiliates and subsidiaries offering health coverage plans to enrolled members. The Plan operates in Massachusetts under the trade name Boston Medical Center HealthNet Plan and in other states under the trade name WellSense New Hampshire Health Plan.

Policy Revisions History

	Commonwealth Choice, and Employer Choice because the products are no longer available. Updated references.		
11/25/15	Review for effective date 01/01/16. Revised language in the Applicable Coding section.	01/01/16 Version 13	11/25/15: MPCTAC (electronic vote) 12/09/15: QIC
09/01/16	Review for effective date 11/01/16. Revised policy title. Updated Summary, Description of Item or Service, Definitions, Clinical Background Information, References, and References to Applicable Laws and Regulations sections. Administrative changes made to the Medical Policy Statement and Limitations sections. Added transoral incisionless fundoplication to the list services included in this policy for all Plan products. As of 10/31/16, retired the <i>Transoral Incisionless Fundoplication (TIF) for Gastroesophageal Reflux Disease (GERD)</i> medical policy, policy number OCA 3.4610 (with retired policy formerly applicable for BMCHP products only). Moved the applicable code for TIF (with no code changes) and criteria for TIF (with no criteria revisions) to this policy and continue to list TIF as an experimental and investigational service. Removed ICD-9 diagnosis codes because the use of these codes is no longer considered industry standard.	11/01/16 Version 14	09/21/16: MPCTAC 10/12/16: QIC
09/01/17	Review for effective date 10/01/17. Updated Clinical Background Information, References, and References to Applicable Laws and Regulations sections.	10/01/17 Version 15	09/20/17: MPCTAC
02/01/18	Review for effective date 03/01/18. Updated Policy Summary and Other Applicable Policies sections.	03/01/18 Version 16	02/21/18: MPCTAC
09/01/18	Review for effective date 12/01/18. Administrative changes made to the	12/01/18 Version 17	09/19/18: MPCTAC

Endoscopic Procedures or Magnetic Esophageal Sphincter Augmentation to Treat Gastrointestinal Reflux Disease (GERD) in the Outpatient Setting

* Plan refers to Boston Medical Center Health Plan, Inc. and its affiliates and subsidiaries offering health coverage plans to enrolled members. The Plan operates in Massachusetts under the trade name Boston Medical Center HealthNet Plan and in other states under the trade name WellSense New Hampshire Health Plan.

Policy Revisions History

	Description of Item or Service, Clinical Background Information, References, and Other Applicable Policies sections. Updated the code list in the Applicable Coding section.		
09/01/19	Review for effective date 10/01/19. Revised the policy title. Administrative changes made to the Description of Item or Service, References, and Reference to Applicable Laws and Regulations sections.	10/01/19 Version 18	09/18/19: MPCTAC
04/01/20	Review for effective date 07/01/20. Administrative changes made to the Policy Summary, Description of Item or Service, Definitions, Applicable Coding, Clinical Background Information, References, and Other Applicable Policies sections. Updated criteria in the Medical Policy Statement and Limitations sections.	07/01/20 Version 19	04/15/20: MPCTAC
07/01/20	Review for effective date 10/01/20. Revised the policy title. Administrative changes made to the Policy Summary, Description of Item or Service, Clinical Background Information, and References sections. Criteria added in the Medical Policy Statement and Limitations sections for magnetic esophageal sphincter augmentation. Added procedure code to the Applicable Coding section and industry-wide update made to diagnosis codes (with codes added to existing code range).	10/01/20 Version 20	07/15/20: MPCTAC
08/01/21	Review for effective date 09/01/21. Administrative changes made to the Policy Summary, Medical Policy Statement, Limitations, Definitions, Clinical Background Information, and References sections.	09/01/21 Version 21	08/27/21: MPCTAC (electronic vote)
11/01/21	Review for effective date 12/01/21. Adopted new medical policy template; removed administrative sections,	12/01/21 Version 22	11/17/21: MPCTAC

Endoscopic Procedures or Magnetic Esophageal Sphincter Augmentation to Treat Gastrointestinal Reflux Disease (GERD) in the Outpatient Setting

* Plan refers to Boston Medical Center Health Plan, Inc. and its affiliates and subsidiaries offering health coverage plans to enrolled members. The Plan operates in Massachusetts under the trade name Boston Medical Center HealthNet Plan and in other states under the trade name WellSense New Hampshire Health Plan.

Policy Revisions History

	Medical Policy Statement section renamed Clinical Criteria section, and Limitations section renamed Limitation and Exclusions section. Added WellSense Medicare Advantage HMO as an applicable product effective 01/01/22. Administrative changes made to the Policy Summary, Clinical Criteria, Limitations and Exclusions, Applicable Coding, and References sections.		
--	--	--	--

Next Review Date

07/01/22

Authorizing Entity

MPCTAC

Disclaimer Information: ⁺

Medical Policies are the Plan's guidelines for determining the medical necessity of certain services or supplies for purposes of determining coverage. These Policies may also describe when a service or supply is considered experimental or investigational, or cosmetic. In making coverage decisions, the Plan uses these guidelines and other Plan Policies, as well as the Member's benefit document, and when appropriate, coordinates with the Member's health care Providers to consider the individual Member's health care needs.

Plan Policies are developed in accordance with applicable state and federal laws and regulations, and accrediting organization standards (including NCQA). Medical Policies are also developed, as appropriate, with consideration of the medical necessity definitions in various Plan products, review of current literature, consultation with practicing Providers in the Plan's service area who are medical experts in the particular field, and adherence to FDA and other government agency policies. Applicable state or federal mandates, as well as the Member's benefit document, take precedence over these guidelines. Policies are reviewed and updated on an annual basis, or more frequently as needed. Treating providers are solely responsible for the medical advice and treatment of Members.

The use of this Policy is neither a guarantee of payment nor a final prediction of how a specific claim(s) will be adjudicated. Reimbursement is based on many factors, including member eligibility and benefits on the date of service; medical necessity; utilization management guidelines (when applicable); coordination of benefits; adherence with applicable Plan policies and procedures; clinical coding criteria; claim editing logic; and the applicable Plan – Provider agreement.

Endoscopic Procedures or Magnetic Esophageal Sphincter Augmentation to Treat Gastrointestinal Reflux Disease (GERD) in the Outpatient Setting

⁺ Plan refers to Boston Medical Center Health Plan, Inc. and its affiliates and subsidiaries offering health coverage plans to enrolled members. The Plan operates in Massachusetts under the trade name Boston Medical Center HealthNet Plan and in other states under the trade name WellSense New Hampshire Health Plan.