MASSACHUSETTS

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Medical Policy

Surgical and Transesophageal Endoscopic Procedures to Treat Gastroesophageal Reflux Disease

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Policy Number: 920

BCBSA Reference Number: 7.01.137; 2.01.38 (For Plan internal use only)
NCD/LCD: N/A

Related Policies

- Endoscopic Radiofrequency Ablation or Cryoablation for Barrett's Esophagus, #218
- Injectable Bulking Agents for the Treatment of Urinary and Fecal Incontinence, #471
- Prior Authorization Request Form for Surgical and Transesophageal Endoscopic Procedures to Treat Gastroesophageal Reflux Disease, #956

Policy

Commercial Members: Managed Care (HMO and POS), PPO, and Indemnity

Magnetic esophageal sphincter augmentation to treat gastroesophageal reflux disease is considered **MEDICALLY NECESSARY** when the following criteria are met:[1]

- Patient has a history of severe GERD for ≥1 year with daily symptoms, **AND**
- Patient has tried and failed optimal non-surgical management of symptoms, including lifestyle modification, weight loss (if indicated), and daily proton pump inhibitor use for ≥ 6 months, **AND**
- Patient has proven gastroesophageal reflux by either endoscopy or ambulatory pH monitoring, **AND**
- Patient has evidence of adequate peristalsis by manometry or barium esophagram, **AND**
- None of the following contraindications are present:
  - Morbid obesity (BMI >35)
  - Suspected or known allergies to metals such as iron, nickel, titanium, or stainless steel
  - Grade C or D (LA classification) esophagitis
  - Scleroderma
  - Esophageal stricture or gross esophageal anatomic abnormalities
  - Suspected or confirmed esophageal or gastric cancer
  - Prior esophageal or gastric surgery or endoscopic intervention.

Transoral incisionless fundoplication (TIF) (eg, EsophyX®; MUSE) is considered **MEDICALLY NECESSARY** as a treatment of gastroesophageal reflux disease when the following criteria are met:[1]

- Patient has a history of severe GERD for ≥1 year with daily symptoms, **AND**

- Patient has tried and failed optimal non-surgical management of symptoms, including lifestyle modification, weight loss (if indicated), and daily proton pump inhibitor use for ≥ 6 months, **AND**
- Patient has proven gastroesophageal reflux by either endoscopy, ambulatory pH monitoring, or barium esophagram, **AND**
- None of the following contraindications are present:
    - Hiatal hernia >2cm in axial height and >2cm in greatest transverse dimension
    - Morbid obesity (BMI >35)
    - Esophagitis grade C or D
    - Barrett's esophagus > 2 cm
    - Non-healing esophageal ulcer
    - Fixed esophageal stricture or narrowing
    - Portal hypertension and/or varices
    - Active gastro-duodenal ulcer disease
    - Gastric outlet obstruction or stenosis
    - Gastroparesis
    - Prior esophageal surgery
    - Scleroderma
    - Suspected or confirmed esophageal or gastric cancer.

Transesophageal radiofrequency to create submucosal thermal lesions of the gastroesophageal junction (ie, the Stretta® procedure) is considered **INVESTIGATIONAL** as a treatment of gastroesophageal reflux disease.

Endoscopic submucosal implantation of a prosthesis or injection of a bulking agent (eg, polymethylmethacrylate beads, zirconium oxide spheres) is **INVESTIGATIONAL** as a treatment of gastroesophageal reflux disease.

Prior Authorization Information

Inpatient

- For services described in this policy, precertification/preauthorization **IS REQUIRED** for all products if the procedure is performed **inpatient**.

Outpatient

- For services described in this policy, see below for products where prior authorization **might be required** if the procedure is performed **outpatient**.

	Outpatient
Commercial Managed Care (HMO and POS)	Prior authorization is **required**.
Commercial PPO	Prior authorization is **required**.

Requesting Prior Authorization Using Authorization Manager

Providers will need to use Authorization Manager to submit initial authorization requests for services. Authorization Manager, available 24/7, is the quickest way to review authorization requirements, request authorizations, submit clinical documentation, check existing case status, and view/print the decision letter. For commercial members, the requests must meet medical policy guidelines.

To ensure the request is processed accurately and quickly:

- Enter the facility's NPI or provider ID for where services are being performed.
- Enter the appropriate surgeon's NPI or provider ID as the servicing provider, *not* the billing group.

Authorization Manager Resources

- Refer to our Authorization Manager page for tips, guides, and video demonstrations.

Complete Prior Authorization Request Form for Surgical and Transesophageal Endoscopic Procedures to Treat Gastroesophageal Reflux Disease (956) using Authorization Manager.

For out of network providers: Requests should still be faxed to 888-282-0780.

CPT Codes / HCPCS Codes / ICD Codes

Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage as it applies to an individual member.

Providers should report all services using the most up-to-date industry-standard procedure, revenue, and diagnosis codes, including modifiers where applicable.

The following codes are included below for informational purposes only; this is not an all-inclusive list.

The above medical necessity criteria MUST be met for the following codes to be covered for Commercial Members: Managed Care (HMO and POS), PPO, Indemnity Medicare HMO Blue and Medicare PPO Blue:

CPT Codes

CPT codes:	Description
43210	Esophagogastroduodenoscopy, flexible, transoral; with esophagogastric fundoplasty, partial or complete, includes duodenoscopy when performed
43284	Laparoscopy, surgical, esophageal sphincter augmentation procedure, placement of sphincter augmentation device (ie, magnetic band), including cruroplasty when performed

ICD-10 Procedure Codes

ICD-10-PCS procedure codes:	Code Description
0DV48ZZ	Restriction of Esophagogastric Junction, Via Natural or Artificial Opening Endoscopic
0DV44CZ	Restriction of Esophagogastric Junction with Extraluminal Device, Percutaneous Endoscopic Approach

The following CPT codes are considered investigational for Commercial Members: Managed Care (HMO and POS), PPO, and Indemnity, Medicare HMO Blue and Medicare PPO Blue:

CPT Codes

CPT codes:	Code Description
43201	Esophagoscopy, flexible, transoral; with directed submucosal injection(s), any substance
43212	Esophagoscopy, flexible, transoral; with placement of endoscopic stent (includes pre- and post-dilation and guide wire passage, when performed)
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

Description

Gastroesophageal Reflux Disease

Gastroesophageal reflux disease (GERD) is defined as reflux of stomach acid into the esophagus that causes symptoms and/or mucosal injury. GERD is a common medical disorder, with estimates of 10% to 20% prevalence in developed countries. The severity of GERD varies widely. Many individuals have mild, intermittent symptoms that do not require treatment or only require episodic use of medications. Other

individuals have chronic, severe GERD that can lead to complications such as Barrett esophagus and esophageal cancer.

Treatment
For individuals with severe disease, chronic treatment with acid blockers is an option. For some individuals, medications are inadequate to control symptoms; other individuals prefer to avoid the use of indefinite, possibly lifelong medications. Surgical treatments are available for these individuals, primarily a Nissen fundoplication performed either laparoscopically or by open surgery. A number of less invasive procedures are also being evaluated as an intermediate option between medical therapy and surgery.

The LINX Reflux Management System is composed of a small flexible band of 10 to 18 interlinked titanium beads with magnetic cores. Using standard laparoscopic techniques, the band is placed around the esophagus at the level of the gastroesophageal junction. The magnetic attraction between the beads is intended to augment the lower esophageal sphincter to prevent gastric reflux into the esophagus, without compressing the esophageal wall. It is proposed that swallowing food or liquids creates sufficient pressure to overcome the magnetic bond between the beads, allowing the beads to separate and temporarily increase the size of the ring. The target population is individuals who have GERD symptoms despite maximum medical therapy (eg, proton pump inhibitors) but who do not want to risk the adverse effects of a surgical procedure like Nissen fundoplication. Adverse events of the LINX Reflux Management System may include dysphagia or odynophagia. The device can be removed by a laparoscopic procedure if severe adverse events occur or if magnetic resonance imaging is needed for another condition.

Summary

A laparoscopically implanted ring composed of interlinked titanium beads with magnetic cores has been developed for the treatment of gastroesophageal reflux disease (GERD). The device is placed around the esophagus at the level of the gastroesophageal junction and is being evaluated in patients who have GERD symptoms, despite maximal medical therapy.

For individuals who have GERD who receive magnetic sphincter augmentation (MSA), the evidence includes 1 randomized controlled trial (RCT) comparing MSA to proton pump inhibitor (PPI) therapy, a single nonrandomized registry study comparing MSA to laparoscopic fundoplication, single-arm cohort studies, and systematic reviews of observational studies comparing MSA to laparoscopic Nissen fundoplication (LNF). Relevant outcomes are symptoms, change in disease status, medication use, and treatment-related morbidity. An RCT comparing MSA to omeprazole 20 mg twice daily found significantly more patients who received MSA reported improvements in symptoms and quality of life (QOL) at 6 months. A major limitation of the trial was that the patients had not received optimal medical treatment prior to enrollment. A prospective, observational registry study comparing MSA to laparoscopic fundoplication found similar improvements in QOL, satisfaction, and medication use. Limitations of the study included lack of randomization and blinding, heterogeneity in fundoplication techniques, use of an outdated MSA protocol, and selection bias as patients with less severe symptoms received MSA. In the 2 single-arm, uncontrolled pivotal trials submitted to the U.S. Food and Drug Administration with materials for device approval, subjects showed improvements in GERD-health-related QOL scores and reduced PPI use. Similarly, observational comparative studies included in systematic reviews, most often comparing MSA with LNF, generally have shown that GERD-health-related QOL scores do not differ significantly between fundoplication and MSA, and patients can reduce PPI use after MSA. However, the comparative studies are retrospective and nonrandomized, and may be affected by selection bias. Randomized comparisons of MSA with LNF are needed to evaluate the relative risk-benefit of these 2 procedures. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Policy History

Date	Action
1/2025	Annual policy review. Policy updated with literature review through September 23, 2024; references added. Policy statement unchanged.

9/2023	Policy clarified to include prior authorization requests using Authorization Manager.
1/2023	Annual policy review. References updated. Policy statements unchanged.
6/2022	Prior authorization information clarified for PPO plans. Effective 6/1/2022.
2/2022	Policy clarified.
1/2022	Annual policy review. Description, summary, and references updated. Policy statements unchanged.
4/2021	Medicare information removed. See MP #132 Medicare Advantage Management for local coverage determination and national coverage determination reference.
1/2021	Annual policy review. Description, summary, and references updated. Policy statements unchanged.
1/2020	Annual policy review. Description, summary, and references updated. Policy statements unchanged.
1/2019	Annual policy review. Description, summary and references updated. Policy statements unchanged.
10/2018	New medically necessary indications described. Title changed. Clarified coding information. Effective 10/1/2018. The following ongoing investigational statements were transferred from policy 635: • Transesophageal radiofrequency to create submucosal thermal lesions • Endoscopic submucosal implantation of a prosthesis or injection of a bulking agent.
1/2017	Annual policy review. Title changed. New references added.
1/2016	Clarified coding information.
11/2015	Annual policy review. New references added.
7/2015	Clarified coding information.
10/2014	Annual policy review. New references added.
1/2014	Updated to add new HCPCS code C9737.
12/2013	Annual policy review. New references added.
3/2013	New policy describing non-coverage. Effective 3/1/2013.

Information Pertaining to All Blue Cross Blue Shield Medical Policies

Click on any of the following terms to access the relevant information:

Medical Policy Terms of Use
Managed Care Guidelines
Indemnity/PPO Guidelines
Clinical Exception Process
Medical Technology Assessment Guidelines

References

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Endnotes

[1] Based on expert opinion