



## MEDICAL POLICY

Date Reviewed: 02/16/07, 05/15/08, 04/24/09, 04/28/10, 04/15/11

**Subject:** Gastroesophageal Reflux Disease (GERD) Endoscopic Treatment (Bard EndoCinch Suturing System, BESS, Enteryx, Esophyx, Gatekeeper, Plicator, StomaphyX, Stretta)

**Description:** Gastroesophageal reflux disease (GERD) is a condition that is the result of the stomach contents leaking back into the esophagus due to malfunction of the lower esophageal sphincter (LES). The refluxed acid causes a burning sensation in the esophagus commonly called heartburn. Heartburn that occurs more than two times a week is usually considered GERD. Several endoscopic procedures to minimize or eliminate GERD have been used. These procedures are performed through the mouth and esophagus using special endoscopic devices, in contrast to other surgical procedures requiring a laparoscopic or open abdominal approach to repair the stomach and esophagus. In one procedure, radiofrequency energy is delivered to the tissue surrounding the LES through endoscopically placed needles (Stretta). This causes tightening of the LES, reducing or eliminating reflux. Other systems use sutures placed in the lower esophagus to improve the function of the LES (EndoCinch, BESS, Plicator). There are also systems where substances are injected into or around the LES to limit reflux (Enteryx, Gatekeeper). (The Enteryx product was recalled due to multiple adverse effects, including death, and is no longer available.)

**Indications of Coverage:**

None

**Limitations of Coverage:**

Review contract and endorsements for exclusions and prior authorization or benefit requirements.

Endoscopic treatment of GERD, including radiofrequency therapy, endoscopic suturing procedures, and injection procedures are considered investigational as there is insufficient peer-reviewed scientific literature supporting the effectiveness of these procedures.

**Documentation required:**

Procedure report

**Rationale:** The standard surgical treatment for individuals with GERD unresponsive to conservative treatment is open or laparoscopic Nissen fundoplication. There is insufficient information supporting the superior effectiveness of the various endoscopic treatments over standard evidence-based treatments. An American Gastroenterological Association consensus panel noted that the use of endoscopic treatments is increasing, even though there is little data regarding the effectiveness of the treatments. Controlled clinical trials documenting that endoscopic treatments significantly reduce or eliminate the need for anti-GERD medications are not available. Similarly, studies evaluating the long-term results of endoscopic treatments have not been completed.

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*Approved by the Medical Director*