BlueCross BlueShield of Arizona
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MEDICAL COVERAGE GUIDELINES
SECTION: SURGERY

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TRANSESOPHAGEAL ENDOSCOPIC THERAPIES FOR GASTROESOPHAGEAL REFLUX DISEASE

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Medical Coverage Guideline must be read in its entirety to determine coverage eligibility, if any.

The section identified as "Description" defines or describes a service, procedure, medical device or drug and is in no way intended as a statement of medical necessity and/or coverage.

The section identified as "Criteria" defines criteria to determine whether a service, procedure, medical device or drug is considered medically necessary or experimental or investigational.

State or federal mandates, e.g., FEP program, may dictate that any drug, device or biological product approved by the U.S. Food and Drug Administration (FDA) may not be considered experimental or investigational and thus the drug, device or biological product may be assessed only on the basis of medical necessity.

Medical Coverage Guidelines are subject to change as new information becomes available.

For purposes of this Medical Coverage Guideline, the terms "experimental" and "investigational" are considered to be interchangeable.

Description:

The following minimally invasive therapies have been investigated as alternatives to open or laparoscopic fundoplication for the treatment of gastroesophageal reflux disease (GERD).

Transesophageal Endoscopic Gastroplasty:
Sutures are placed in the lower esophageal sphincter to strengthen and lengthen the sphincter to decrease reflux. Transesophageal endoscopic gastroplasty can also be referred to as gastroplication, fundoplication, transoral incisionless fundoplication (TIF), natural orifice surgery (NOS) or natural orifice transluminal surgery (NOTES). FDA approved devices include EndoCinch™, EsophyX® and NDO Plicator™.

TRANSESOPHAGEAL ENDOSCOPIC THERAPIES FOR GASTROESOPHAGEAL REFLUX DISEASE (cont.)

Description: (cont.)

Transesophageal Radiofrequency (Stretta Procedure):
The CSM Stretta® System uses radiofrequency energy to create thermal lesions in the esophageal wall at multiple sites above and below the esophageal junction. The mechanism of action is not precisely known but may be related to the ablation of nerve pathways responsible for sphincter relaxation or may induce a tightening of tissue due to heat induced collagen contraction. The Stretta device has been FDA-approved.

Endoscopic Submucosal Injection or Implantation of Prosthetic or Bulking Agent: Injection or implantation of an agent to enhance the volume and create bulk of the lower esophageal sphincter. Agents that have been investigated include:

- Enteryx™ is a biocompatible liquid polymer which received FDA approval in 2003. Enteryx was voluntarily recalled by the manufacturer 09/23/05 due to adverse side effects and is no longer being marketed.
- Durasphere® is a bulking agent of carbon-coated zirconium oxide spheres that is FDA-approved for urinary and fecal incontinence. Durasphere has been investigated for GERD as an off-label use.
- Gatekeeper™ Reflux Repair System is a soft, pliable, expandable prosthesis implanted into the esophageal submucosa which absorbs water and expands to create bulk. Gatekeeper has not received FDA approval and the clinical trial was terminated in 2005 for lack of efficacy.
- Endoscopic submucosal implantation of gelatinous polymethylmethacrylate (PMMA) beads into the folds of the lower esophagus.

TRANSESOPHAGEAL ENDOSCOPIC THERAPIES FOR GASTROESOPHAGEAL REFLUX DISEASE (cont.)

Criteria:

- The following procedures for the treatment of gastroesophageal reflux disease (GERD) are considered ***experimental or investigational*** based upon:

  1. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes, and
  2. Insufficient evidence to support improvement of the net health outcome, and
  3. Insufficient evidence to support improvement of the net health outcome as much as, or more than, established alternatives, and
  4. Insufficient evidence to support improvement outside the investigational setting.

  These procedures include, *but are not limited to:*

  - Endoscopic submucosal implantation of a prosthesis or bulking agent
    - Biocompatible liquid polymers (Enteryx)
    - Polymethylmethacrylate (PMMA) beads
    - Zirconium oxide spheres (Durasphere)

  - Transesophageal endoscopic gastroplasty (fundoplication, gastroplication, NOS, TIF)
    - EndoCinch
    - EsophyX
    - NDO Plicator
    - StomaphyX

  - Transesophageal radiofrequency
    - Stretta procedure

TRANSESOPHAGEAL ENDOSCOPIC THERAPIES FOR GASTROESOPHAGEAL REFLUX DISEASE (cont.)

Resources:

1. 2.01.38 BCBS Association Medical Policy Reference Manual. Transesophageal Endoscopic Therapies for Gastroesophageal Reflux Disease. Re-issue date 11/14/2013, issue date 12/15/2000.

2. Bell R, Mavrelis P, et al. A Prospective Multicenter Registry of Patients with Chronic Gastroesophageal Reflux Disease Receiving Transoral Incisionless Fundoplication. *J Am Coll Surg.* 12/2012;215(6):794-809.

FDA Premarket Approval Database for Enteryx™ Procedure Kit:

- FDA-approved indication: Endoscopic injection into the region of the lower esophageal sphincter (LES) for the treatment of gastroesophageal reflux disease (GERD) symptoms in patients responding to and requiring daily pharmacological therapy with proton pump inhibitors. ***Manufacturer Boston Scientific Corporation recalled all Enteryx Procedure Kits and Enteryx Single Pack Injectors effective 09/23/05.**

FDA 510K Summary for EndoCinch™ Suturing System:

- FDA-approved indication: For endoscopic placement of suture(s) in the soft tissue of the esophagus and stomach and for approximation of tissue for the treatment of symptomatic gastroesophageal reflux disease.

FDA 510K Summary for EsophyX® System:

- FDA-approved indication: For use in endoluminal, transoral tissue approximation, full thickness plication and ligation in the GI tract and is indicated for the treatment of symptomatic chronic gastroesophageal reflux disease in patients who require and respond to pharmacological therapy. It is also indicated to narrow the gastroesophageal junction and reduce hiatal hernia <= 2 cm in size in patients with symptomatic chronic gastroesophageal reflux disease.

TRANSESOPHAGEAL ENDOSCOPIC THERAPIES FOR GASTROESOPHAGEAL REFLUX DISEASE (cont.)

Resources: (cont.)

FDA 510K Summary for NDO™ Plicator:

- FDA-approved indication: For the treatment of the symptoms of chronic gastroesophageal reflux disease (GERD) in patients who require and respond to pharmacological therapy.

FDA 510K Summary for Stretta® System:

- FDA-approved indication: For general use in the electrosurgical coagulation of tissue and intended for use specifically in the treatment of gastroesophageal reflux disease (GERD).