Geisinger

POLICIES AND PROCEDURE MANUAL

Policy: MP256

Section: Medical Benefit Policy

Subject: Transoral Incisionless Fundoplication

I. Policy: Transoral Incisionless Fundoplication

II. Purpose/Objective:

To provide a policy of coverage regarding Transoral Incisionless Fundoplication

III. Responsibility:

A. Medical Directors
B. Medical Management

IV. Required Definitions

1. Attachment – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. Exhibit – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. Devised – the date the policy was implemented.
4. Revised – the date of every revision to the policy, including typographical and grammatical changes.
5. Reviewed – the date documenting the annual review if the policy has no revisions necessary.

V. Additional Definitions

Medical Necessity or Medically Necessary means Covered Services rendered by a Health Care Provider that the Plan determines are:

a. appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
b. provided for the diagnosis, and the direct care and treatment of the Member's condition, illness disease or injury;
c. in accordance with current standards of good medical treatment practiced by the general medical community.
d. not primarily for the convenience of the Member, or the Member's Health Care Provider; and
e. the most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

Medicaid Business Segment

Medical Necessity shall mean a service or benefit that is compensable under the Medical Assistance Program and if it meets any one of the following standards:

(i) The service or benefit will, or is reasonably expected to, prevent the onset of an illness, condition or disability.
(ii) The service or benefit will, or is reasonably expected to, reduce or ameliorate the physical, mental or development effects of an illness, condition, injury or disability.
(iii) The service or benefit will assist the Member to achieve or maintain maximum functional capacity in performing daily activities, taking into account both the functional capacity of the Member and those functional capacities that are appropriate for members of the same age.

DESCRIPTION:
Transoral Incisionless Fundoplication, including but not limited to the EndoGastric Solutions SerosaFuse™ implantable fasteners, and associated EsophyX delivery device and accessories consist of sterile polypropylene fastener implants and an ergonomic, flexible fastener delivery. The EndoGastric Solutions (EGS) EsophyXTM System with SerosaFuse™Fastener is indicated 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 < 2cm in size in patients with symptomatic chronic gastroesophageal reflux disease.

INDICATIONS: **REQUIRES PRIOR AUTHORIZATION BY A PLAN MEDICAL DIRECTOR OR DESIGNEE**

COMMERCIAL BUSINESS SEGMENT
Transoral incisionless fundoplication is covered when all of the following criteria are met:

- Member is 18 years of age or greater; and
- A diagnosis of GERD has been established by endoscopy, ambulatory pH testing or barium swallow; and
- Member has a history of daily bothersome GERD symptoms inadequately controlled with individually maximized daily PPI use (unless intolerant to or contraindicated) for at least 6 months; and
- Documentation of gastroesophageal valve (Hill grade I – II) at gastroesophageal junction (**UNLESS** TIF is being done in conjunction with laparoscopic repair of the hiatus)*; and
- Member has a BMI of 35 or less; and
- None of the following are present:
    - Hiatal hernia greater than 2 cm (unless simultaneous or prior repair of hiatal hernia is performed)
    - Esophagitis grade C or D **
    - Barrett's esophagus greater than 2 cm
    - Esophageal ulcer, stricture or narrowing
    - Portal hypertension and/or varices
    - Active gastro-duodenal ulcer
    - Gastric outlet obstruction or stenosis
    - Symptomatically uncontrolled gastroparesis
    - History of uncontrolled or untreated coagulation disorder
    - Cervical spine fusion
    - Zenker's diverticulum

Even if someone had a more major resection as long as they had enough stomach to maneuver the device they would certainly be a candidate in my mind. In fact, some patients who have had multiple previous operations in that region including gastric resections may make some of the better candidates for the procedure because they are keeping you out of a hostile abdomen.

*Note: Hill Classification

1.Type I hernias are sliding hiatal hernias, where the gastroesophageal junction migrates above the diaphragm6. The stomach remains in its usual longitudinal alignment and the fundus remains below the gastroesophageal junction.
2.Type II hernias are pure paraesophageal hernias (PEH); the gastroesophageal junction remains in its normal anatomic position but a portion of the fundus herniates through the diaphragmatic hiatus adjacent to the esophagus.
3.Type III hernias are a combination of Types I and II, with both the gastroesophageal junction and the fundus herniating through the hiatus. The fundus lies above the gastroesophageal junction.
4.Type IV hiatal hernias are characterized by the presence of a structure other than stomach, such as the omentum, colon or small bowel within the hernia sac.

Hill AD, Kozarek RA, Kraemer SJM, Aye RW, Mercer D, Low DE,Pope CE II (1996) The gastroesophageal flap valve: in vitro and in vivo observations. Gastrointest Endosc 44: 541–547

** Los Angeles (LA) Grading of Esophagitis

A. Mucosal break(s) ≤5 mm, without continuity across mucosal folds
B. Mucosal break(s) >5 mm, without continuity across mucosal folds
C. Mucosal break(s) continuous between ≥2 mucosal folds, involving <75% of the esophageal circumference
D. Mucosal break(s) involving ≥75% of the esophageal circumference

Katz PO, Gerson LB, et al. Guideline for the diagnosis and management of gastroesophageal reflux disease. Am J Gastroenterol. 2013;108(3):308-328.

MEDICARE BUSINESS SEGMENT:

Transoral incisionless fundoplication is covered for the following indications:

- Symptomatic chronic gastroesophageal reflux (chronic being defined as > 6 months of symptoms), and
- Symptoms must be responsive to Proton Pump Inhibitors (PPIs) as judged by GERD HRQL scores of < or equal to 12 while on PPIs and > or equal to 20 when off for 14 days (also acceptable would be the difference of > or equal to 10 of the scores between off and on therapy), and
- Hiatal hernia < or equal to 2 cm, if present.

MEDICAID BUSINESS SEGMENT:

Transoral incisionless fundoplication is **NOT** a covered Medicaid benefit. Consideration through a Program Exception is required.

EXCLUSIONS:

The Plan does **NOT** provide coverage for Transoral Incisionless Fundoplication, including but not limited to the EndoGastric Solutions SerosaFuse™ implantable fasteners, and associated EsophyX delivery device, when the criteria for coverage are not met.

Note: A complete description of the process by which a given technology or service is evaluated and determined to be experimental, investigational or unproven is outlined in MP 15 - Experimental Investigational or Unproven Services or Treatment.

CODING ASSOCIATED WITH: Transoral Incisionless Fundoplication
The following codes are included below for informational purposes and may not be all inclusive. Inclusion of a procedure or device code(s) does not constitute or imply coverage nor does it imply or guarantee provider reimbursement. Coverage is determined by the member specific benefit plan document and any applicable laws regarding coverage of specific services. Please note that per Medicare coverage rules, only specific CPT/HCPCS Codes may be covered for the Medicare Business Segment. Please consult the CMS website at www.cms.gov ***or the local Medicare Administrative Carrier (MAC) for more information on Medicare coverage and coding requirements.***

43210 – Esophogastroduodenoscopy with esophagogastric fundoplasty, partial or complete, includes duodenoscopy when performed
43499 – Unlisted procedure, esophagus

LINE OF BUSINESS:
Eligibility and contract specific benefits, limitations and/or exclusions will apply. Coverage statements found in the line of business specific benefit document will supersede this policy. For Medicare, applicable LCD's and NCD's will supercede this policy. For PA Medicaid Business segment, this policy applies as written.

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This policy will be revised as necessary and reviewed no less than annually.

Devised: 6/11

Revised: 12/12 (changed Medicare criteria); 5/19 (Added Commercial Business Segment); 5/20 (revised criteria)

Reviewed: 6/12, 12/13, 12/14, 5/15, 5/16, 4/17, 4/18