

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.

LIMITATIONS:

FOR 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.

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, because it is considered **experimental, investigational or unproven**. The Geisinger Technology Assessment Committee evaluated this technology and concluded that there is insufficient evidence in the peer-reviewed published medical literature to establish the effectiveness of this technology on health outcomes when compared to established tests or technologies.

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.

43499 – Unlisted procedure, esophagus

Current Procedural Terminology (CPT®) © American Medical Association: Chicago, IL

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 supersede 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)

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