Clinical Coverage Guidelines: **Transoral Incisionless Fundoplication (TIF) with the EsophyX System for Gastroesophageal Reflux Disease (GERD)**

**Current Effective Date:** 09/01/12  
**Original Effective Date:** 09/01/11*  
**Policy Number:** OCA: 3.461  
**Product Applicability:**  
- MassHealth  
- Commonwealth Care  
- Commercial

**Summary:** The Plan considers the transoral incisionless fundoplication (TIF) with the EsophyX System for GERD medically necessary for the treatment of symptomatic chronic gastroesophageal reflux disease as outlined in the criteria below. All other endoscopic treatments for GERD are considered experimental and investigational.

**Description of Item or Service:**
**Transoral Incisionless Fundoplication (TIF) with the EsophyX Device:** A procedure that provides an incisionless solution for the treatment of GERD. The device is inserted through the patient's mouth, under visual guidance of an endoscope and used to construct an antireflux valve to tighten the LES (lower esophageal sphincter), reestablishing a barrier to reflux and restoring the competency of the gastroesophageal junction.

**Clinical Guideline Statement:**
1. The Plan considers transoral incisionless fundoplication (TIF) with the EsophyX device medically necessary for the treatment of symptomatic chronic gastroesophageal reflux disease when performed by a physician trained in this procedure in patients who do not have a hiatal hernia greater than 2 cm and who have failed all standard medical therapies including pharmacological therapy for any of the following indications:
   - Persistent GERD symptoms despite treatment with maximum doses of a specific proton pump inhibitor (PPI) for a minimum of a four (4) week period of time
   - Anatomic disruption of the gastroesophageal (GE) flap valve to a Hill Grade II-III.
   - Evidence of one of the following while on PPI therapy:
     a. Erosive esophagitis (erosions or ulcerations during endoscopy)

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**BMC HealthNet Plan – EsophyX**

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2. Contraindications for TIF include all of the following:
   - BMI ≥ 35
   - Hiatal hernia > 2 cm
   - Esophagitis grade D or Barrett’s esophagitis
   - Esophageal ulcer or varices
   - Ineffective esophageal motility
   - Fixed esophageal stricture or narrowing
   - Portal hypertension and/or varices
   - History of previous resective gastric or esophageal surgery, cervical spine fusion, Zenker's diverticulum, esophageal epiphrenic diverticulum, achalasia, scleroderma or dermatomyositis, eosinophilic esophagitis, > 2 dilations for esophageal stricture, or cirrhosis
   - Active esophago-gastro-duodenal ulcer disease
   - Gastric outlet obstruction or stenosis
   - Gastroparesis or delayed gastric emptying confirmed by solid-phase gastric emptying study if patient complains of postprandial satiety during assessment
   - Active bleeding disorder
   - Tobacco and alcohol abuse
   - Non-compliance to appropriate pharmacological treatment
   - Non-compliance to the elimination of lifestyle changes such as diet modifications

Additional Definitions:
**Gastroesophageal Reflux Disease (GERD):** A chronic abnormal regurgitation of gastric contents into the esophagus causing severe and persistent physical discomfort. Symptoms of GERD include heartburn, pain, dysphagia, and/or tissue damage and are caused by the failure of the sphincter mechanism at the gastroesophageal junction. There are three (3) classifications of GERD:

1. Non-erosive esophagitis (NERD): Inflammation of the esophagus without esophageal injury.

2. Erosive esophagitis: Inflammation of the esophagus causing breaks or erosions in the lining of the esophagus. There are four grades of esophagitis:
   - Grade A Mucosal break ≤ 5 mm in length
   - Grade B Mucosal break > 5 mm
   - Grade C Mucosal break continuous between > 2 mucosal folds
   - Grade D Mucosal break ≥ 75% of esophageal circumference

3. Barrett’s esophagus: An abnormal change in the cells of the esophagus caused by chronic inflammation and acid exposure from reflux esophagitis.
Hill Classification of Gastroesophageal Flap Valve (GEFV) Grade:
I and II are classified as normal and grades III and IV are abnormal.
- Grade I: Prominent fold of tissue along the lesser curvature that was closely apposed to the endoscope
- Grade II: Fold was present but there would be periods of opening and rapid closing around the endoscope
- Grade III: Fold was not prominent and the endoscope was not gripped tightly by the tissues
- Grade IV: There was no fold and the lumen of the esophagus gaped open, allowing the squamous epithelium to be viewed from below

Applicable Coding:
Codes may not be all inclusive as the American Medical Association (AMA) code updates may occur more frequently or at different intervals than policy updates. These codes are not intended to be used for coverage determinations.

<table>
<thead>
<tr>
<th>CPT Codes</th>
<th>Description</th>
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<tbody>
<tr>
<td>43499</td>
<td>Unlisted procedure, esophagus</td>
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<tr>
<td>43999</td>
<td>Unlisted procedure, stomach</td>
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</tbody>
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Limitations: All other endoscopic treatments for GERD are considered experimental and investigational. See clinical policy entitled Endoscopic Treatment for GERD.

Clinical Background Information:
Gastroesophageal reflux disease (GERD) is one of the most common disorders of the GI tract. Many individuals with GERD suffer from a spectrum of symptoms ranging from occasional heartburn and regurgitation to persistent esophageal tissue damage potentially leading to serious complications. Symptoms can include a burning acid feeling in the throat and chest, dysphagia, chronic cough, wheezing, hoarseness, chest pain, nausea and belching. The goal of initial treatment for GERD is the reduction of esophageal reflux by lifestyle modification, diet and medications. Mild disease can usually be managed through dietary or lifestyle changes and over-the-counter medications such as antacids. Moderate disease is characterized by failure of the above treatments and more persistent symptoms and usually can be managed with drugs that inhibit acid secretion and improve gastric motility such as H2 blockers and Proton Pump Inhibitors (PPI). Severe disease may or may not be associated with serious complications such as esophagitis, esophageal ulceration or stricture, and metastatic changes. Severe disease is usually treated with lifelong medication or surgery, such as fundoplication (the fundus of the stomach is wrapped around the stomach to create an anti-reflux barrier between the stomach and the esophagus). Surgery is reserved for those patients with severe disease in whom medical therapy has failed. Common causes of GERD include a malfunction of the LES, impaired gastric emptying, and failed esophageal peristalsis. Certain agents are known to...
delay stomach emptying such as alcohol, caffeine, peppermint and fatty foods. A thorough diagnostic evaluation is necessary before the appropriate course of therapy for GERD can be determined. Commonly performed tests include upper endoscopy with biopsy; esophageal motility/manometry and a pH study.

A new procedure for the treatment of GERD is the transoral incisionless fundoplication (TIF) with the EndoGastric Solutions (EGS) EsophyX™ System with Serofuse™ Fastener device. The TIF procedure does not require an incision and the EsophyX device is inserted through the patient's mouth, under visual guidance of an endoscope to construct an antireflux valve to tighten the LES (lower esophageal sphincter), reestablishing a barrier to reflux and restoring the competency of the gastroesophageal junction. The procedure takes about 90 minutes using general, local or conscious sedation and is typically performed on the day of hospital admission. In general, patients are discharged from the hospital on the second postoperative day or when the patient is stable on oral therapy for pain and can tolerate oral intake of food. The most common complications are dysphagia and inability to belch or vomit. This device 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.

References:


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Policy History:
Original Effective Date: 09/01/11
*Effective Date for Commercial is 01/01 12

Date of Review/Revision:
05/01/12: Annual review and updated references. Deleted CPT code 43659 (unlisted laparoscopic procedure, stomach) as an applicable code and replaced with applicable CPT codes 43499 (unlisted procedure, esophagus) and 43999 (unlisted procedure, stomach). Added “ineffective esophageal motility” to the list of contraindications for TIF based on clinical review.

Last Review Date:
5/01/12

Next Review Date:
10/01/12

Approval Dates:
Regulatory Approval: N/A
Internal Approval:
05/16/12: MPCTAC
06/27/12: QIC

Authorizing Entity:
QIC

IMPORTANT NOTE: Not all services are covered for all products or employer groups. This medical policy expresses the Plan's determination of whether certain services or supplies are medically necessary, experimental or investigational or cosmetic. The Plan has reached these conclusions based upon the regulatory status of the technology and a review of clinical studies published in peer-reviewed medical literature. Even though this policy may indicate that a
particular service or supply is considered covered or not covered, this conclusion is not based upon the terms of a member’s particular benefit plan. Each benefit plan contains its own specific provisions for coverage and exclusions. Not all services that are determined to be medically necessary will necessarily be covered services under the terms of a member’s benefit plan. Members and their providers need to consult the applicable benefit plan document (e.g., Evidence of Coverage) to determine if there are any exclusions or other benefit limitations applicable to this service or supply. If there is a discrepancy between this medical policy and the benefit plan document, the provisions of the benefit plan document will govern. In addition, this policy and the benefit plan document are subject to applicable state and federal laws that may mandate coverage for certain services and supplies.