Medical Policy

Transoral Incisionless Fundoplication (TIF) with the EsophX System for Gastroesophageal Reflux Disease (GERD)

Policy Number: OCA 3.461
Version Number: 7
Version Effective Date: 03/01/16

Product Applicability

- All Plan+ Products
- Well Sense Health Plan
  - New Hampshire Medicaid
  - NH Health Protection Program
- Boston Medical Center HealthNet Plan
  - MassHealth
  - Qualified Health Plans/ConnectorCare/Employer Choice Direct
  - Senior Care Options ◊

Notes:
+ Disclaimer and audit information is located at the end of this document.
◊ The guidelines included in this Plan policy are applicable to members enrolled in Senior Care Options only if there are no criteria established for the specified service in a Centers for Medicare & Medicaid Services (CMS) national coverage determination (NCD) or local coverage determination (LCD) on the date of the prior authorization request. Review the member’s product-specific benefit documents at www.SeniorsGetMore.org to determine coverage guidelines for Senior Care Options.

Policy Summary

Generally, the Plan considers transoral incisionless fundoplication (TIF) with the EsophyX System to be experimental and investigational when used for the treatment of symptomatic chronic gastroesophageal reflux disease (GERD) or for any other indication. It will be determined during the Plan’s standard prior authorization review process if the service is considered experimental and investigational for the requested use.
See the Plan’s policy, *Experimental and Investigational Treatment* (policy number OCA 3.12), for the product-specific definitions of experimental or investigational treatment. All other endoscopic treatments for GERD are considered experimental and investigational, as specified in Plan policy, *Endoscopic Treatments for GERD* (policy number OCA 3.46).

**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 lower esophageal sphincter (LES), reestablishing a barrier to reflux and restoring the competency of the gastroesophageal junction.

**Medical Policy Statement**

The Plan considers transoral incisionless fundoplication (TIF) with the EsophyX System to be experimental and investigational when used for the treatment of symptomatic chronic gastroesophageal reflux disease (GERD) or for any other indication.

**Limitations**

The Plan considers transoral incisionless fundoplication (TIF) with the EsophyX System to be experimental and investigational.

**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. **Barrett’s Esophagus:** An abnormal change in the cells of the esophagus caused by chronic inflammation and acid exposure from reflux esophagitis.

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


**Hill Classification of Gastroesophageal Flap Valve (GEFV) Grade:** I and II are classified as normal and grades III and IV are abnormal.

1. Grade I: Prominent fold of tissue along the lesser curvature that was closely apposed to the endoscope

2. Grade II: Fold was present but there would be periods of opening and rapid closing around the endoscope

3. Grade III: Fold was not prominent and the endoscope was not gripped tightly by the tissues

4. 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**

The Plan uses and adopts up-to-date Current Procedural Terminology (CPT) codes from the American Medical Association (AMA), International Statistical Classification of Diseases and Related Health Problems, 10th revision (ICD-10) diagnosis codes developed by the World Health Organization and adapted in the United States by the National Center for Health Statistics (NCHS) of the Centers for Disease Control under the U.S. Department of Health and Human Services, and the Health Care Common Procedure Coding System (HCPCS) established and maintained by the Centers for Medicare & Medicaid Services (CMS). Because the AMA, NCHS, and CMS may update codes more frequently or at different intervals than Plan policy updates, the list of applicable codes included in this Plan policy is for informational purposes only, may not be all inclusive, and is subject to change without prior notification. Whether a code is listed in the Applicable Coding section of this Plan policy does not constitute or imply member coverage or provider reimbursement. Providers are responsible for reporting all services using the most up-to-date industry-standard procedure and diagnosis codes as published by the AMA, NCHS, and CMS at the time of the service.

Providers are responsible for obtaining prior authorization for the services specified in the Medical Policy Statement section and Limitation section of this Plan policy, even if an applicable code appropriately describing the service that is the subject of this Plan policy is not included in the Applicable Coding section of this Plan policy. Coverage for services is subject to benefit eligibility under the member’s benefit plan. Please refer to the member’s benefits document in effect at the time of the service to determine coverage or non-coverage as it applies to an individual member. See Plan reimbursement policies for Plan billing guidelines.
Transoral Incisionless Fundoplication (TIF) with the EsophyX™ System for Gastroesophageal Reflux Disease (GERD)

Plan refers to Boston Medical Center Health Plan, Inc. and its affiliates and subsidiaries offering health coverage plans to enrolled members. The Plan operates in Massachusetts under the trade name Boston Medical Center HealthNet Plan and in other states under the trade name Well Sense Health Plan.

### CPT Code Description: Code Considered Experimental and Investigational

<table>
<thead>
<tr>
<th>CPT Code</th>
<th>Description: Code Considered Experimental and Investigational</th>
</tr>
</thead>
<tbody>
<tr>
<td>43210</td>
<td>Esophagogastroduodenoscopy, flexible, transoral with esophagogastric fundoplasty, partial or complete, includes duodenoscopy</td>
</tr>
</tbody>
</table>

### Clinical Background Information

Gastroesophageal reflux disease (GERD) is one of the most common disorders of the gastrointestinal (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. Lifestyle modifications include losing weight (if overweight), avoiding large meals, waiting three (3) hours after a meal before lying down, and elevating the head of the bed eight (8) inches. Dietary modifications to decrease the symptoms of GERD may include avoiding alcohol, chocolate, citrus juice, tomato-based products, peppermint, coffee, and onions. Drug therapy to treat the symptoms of GERD includes the use of acid suppressants and antacids, histamine-2 receptor antagonists, or proton pump inhibitors; these medications can lose their effectiveness over time and require progressively higher dosing.

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 (i.e., 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 lower esophageal sphincter (LES), impaired gastric emptying, and failed esophageal peristalsis. 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 more recent procedure used 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 anti-reflux valve to tighten the LES, 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 used in endoluminal, transoral tissue approximation, full thickness plication and ligation in the GI tract and is indicated for the treatment of symptomatic chronic GERD in patients who require and respond to pharmacological therapy. It is also used to narrow the gastroesophageal junction and reduce hiatal hernia < 2 cm in size in patients with symptomatic chronic GERD. At the current time, there is insufficient scientific evidence in the peer reviewed medical literature to support the effectiveness of TIF with the EsophyX System for when used for the treatment of symptomatic chronic GERD or for any other indication.

References


Transoral Incisionless Fundoplication (TIF) with the EsophX System for Gastroesophageal Reflux Disease (GERD)

Plan refers to Boston Medical Center Health Plan, Inc. and its affiliates and subsidiaries offering health coverage plans to enrolled members. The Plan operates in Massachusetts under the trade name Boston Medical Center HealthNet Plan and in other states under the trade name Well Sense Health Plan.


<table>
<thead>
<tr>
<th>Original Approval Date</th>
<th>Original Effective Date* and Version Number</th>
<th>Policy Owner</th>
<th>Approved by</th>
</tr>
</thead>
<tbody>
<tr>
<td>Regulatory Approval: N/A</td>
<td>09/01/11 Version 1</td>
<td>Medical Policy Manager as Chair of Medical Policy, Criteria, and Technology Assessment Committee (MPCTAC) and member of Quality Improvement Committee (QIC)</td>
<td>MPCTAC and QIC</td>
</tr>
<tr>
<td>Internal Approval: 09/01/11</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*Effective Date for the BMC HealthNet Plan Commercial Product(s): 01/01/12

Policy Revisions History

<table>
<thead>
<tr>
<th>Review Date</th>
<th>Summary of Revisions</th>
<th>Revision Effective Date and Version Number</th>
<th>Approved by</th>
</tr>
</thead>
<tbody>
<tr>
<td>05/01/12</td>
<td>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)</td>
<td>Version 2</td>
<td>05/16/12: MPCTAC 06/27/12: QIC</td>
</tr>
</tbody>
</table>

Transoral Incisionless Fundoplication (TIF) with the EsophX System for Gastroesophageal Reflux Disease (GERD)

* Plan refers to Boston Medical Center Health Plan, Inc. and its affiliates and subsidiaries offering health coverage plans to enrolled members. The Plan operates in Massachusetts under the trade name Boston Medical Center HealthNet Plan and in other states under the trade name Well Sense Health Plan.
### Policy Revisions History

<table>
<thead>
<tr>
<th>Date</th>
<th>Description</th>
<th>Version</th>
<th>Reviewing Body</th>
</tr>
</thead>
<tbody>
<tr>
<td>10/01/12</td>
<td>Updated references and Summary section. Revised language in Applicable Coding section. Moved contraindications from Clinical Guidelines section to Limitations section.</td>
<td>Version 3</td>
<td>10/17/12: MPCTAC 11/28/12: QIC</td>
</tr>
<tr>
<td>08/01/13</td>
<td>Review for effective date 12/01/13. Revised Summary, Medical Policy Statement, Limitations, and Clinical Background Information sections to specify that the Plan now considers this service experimental and investigational (based on scientific evidence).</td>
<td>12/01/13 Version 4</td>
<td>08/21/13: MPCTAC 09/19/13: QIC</td>
</tr>
<tr>
<td>09/01/14</td>
<td>Review for effective date 11/01/14. Updated references.</td>
<td>11/01/14 Version 5</td>
<td>09/17/14: MPCTAC 10/08/14: QIC</td>
</tr>
<tr>
<td>09/01/15</td>
<td>Review for effective date 11/01/15. Updated list of applicable products and corresponding notes. Updated References section.</td>
<td>11/01/15 Version 6</td>
<td>09/16/15: MPCTAC 10/14/15: QIC</td>
</tr>
</tbody>
</table>

### Last Review Date

11/25/15

### Next Review Date

09/01/16

### Authorizing Entity

QIC

### Other Applicable Policies

Medical Policy - *Endoscopic Treatments for GERD*, policy number OCA 3.46

*Transoral Incisionless Fundoplication (TIF) with the EsophX System for Gastroesophageal Reflux Disease (GERD)*

Plan refers to Boston Medical Center Health Plan, Inc. and its affiliates and subsidiaries offering health coverage plans to enrolled members. The Plan operates in Massachusetts under the trade name Boston Medical Center HealthNet Plan and in other states under the trade name Well Sense Health Plan.
Medical Policy - *Experimental and Investigational Treatment*, policy number OCA 3.12

**Disclaimer Information:**

Medical Policies are the Plan’s guidelines for determining the medical necessity of certain services or supplies for purposes of determining coverage. These Policies may also describe when a service or supply is considered experimental or investigational, or cosmetic. In making coverage decisions, the Plan uses these guidelines and other Plan Policies, as well as the Member’s benefit document, and when appropriate, coordinates with the Member’s health care Providers to consider the individual Member’s health care needs.

Plan Policies are developed in accordance with applicable state and federal laws and regulations, and accrediting organization standards (including NCQA). Medical Policies are also developed, as appropriate, with consideration of the medical necessity definitions in various Plan products, review of current literature, consultation with practicing Providers in the Plan’s service area who are medical experts in the particular field, and adherence to FDA and other government agency policies. Applicable state or federal mandates, as well as the Member’s benefit document, take precedence over these guidelines. Policies are reviewed and updated on an annual basis, or more frequently as needed. Treating providers are solely responsible for the medical advice and treatment of Members.

The use of this Policy is neither a guarantee of payment nor a final prediction of how a specific claim(s) will be adjudicated. Reimbursement is based on many factors, including member eligibility and benefits on the date of service; medical necessity; utilization management guidelines (when applicable); coordination of benefits; adherence with applicable Plan policies and procedures; clinical coding criteria; claim editing logic; and the applicable Plan – Provider agreement.

---

*Plan refers to Boston Medical Center Health Plan, Inc. and its affiliates and subsidiaries offering health coverage plans to enrolled members. The Plan operates in Massachusetts under the trade name Boston Medical Center HealthNet Plan and in other states under the trade name Well Sense Health Plan.*