Medical Policy

Endoscopic Treatments for GERD in the Outpatient Setting (Including Transoral Incisionless Fundoplication)

Policy Number: OCA 3.46  
Version Number: 15 
Version Effective Date: 10/01/17

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

The Plan considers all endoscopic treatments/transesophageal endoscopic therapies for gastroesophageal reflux disease (GERD) to be experimental and investigational. It will be determined during the Plan’s prior authorization review process if the service is considered experimental and investigational for the requested indication. See the Plan’s Experimental and Investigational Treatment medical policy, policy number OCA 3.12, for the product-specific definitions of experimental or investigational treatment. The Plan considers transoral incisionless fundoplication (TIF) be

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experimental and investigational when used for the treatment of symptomatic GERD or for any other indication; TIF may be done using the EsophyX® device or the Medigus Ultrasonic Surgical Endostapler system (MUSE™). Other examples of endoscopic treatments for GERD include but are not limited to the services summarized in the Description of item of Service section of this policy.

**Description of Item or Service**

**Endoscopic Treatments for GERD/Transesophageal Endoscopic Therapies for GERD:** Minimally invasive outpatient, transesophageal (passing through or performed by way of the esophagus) treatments performed to alter the structure at the gastroesophageal junction to prevent reflux of the gastric contents. These procedures are used as incisionless treatments for symptomatic GERD. Types of endoscopic treatments include but are not limited to the following treatments (or a combination of endoscopic treatments), as specified below in items 1 through 3:

1. **Endoscopic Submucosal Implantation/Endoscopic Injection of Bulking Agents:** Surgical procedure conducted from the inside of the esophagus that inject bulking agents such as Plexiglas polymethylmethacrylate (PMMA) microspheres (Arkema Inc.) or pyrolytic carbon-coated zirconium oxide spheres such as Durasphere® (Carbon Medical Technologies) into the lower esophageal lining. The materials are implant into the submucosa for bulking of the tissues which supposedly will cause constriction and lengthening, resulting in the reduction of reflux. The Enteryx® polymer received FDA approval in 2003; however, on September 23, 2005, Boston Scientific issued a recall of all Enteryx® Procedure Kits and Enteryx® Injector Single Packs from commercial distribution. Serious adverse events, including death, occurred in patients treated with Enteryx®.

2. **Transesophageal Radiofrequency:** Also known as the Stretta® procedure (Curon Medical Inc.), this endoscopic treatment delivers high frequency thermal energy to the smooth muscle of the lower esophageal sphincter (LES), creating thermal lesions to remodel/thicken tissue at the LES and lessen LES relaxations. This treatment is proposed to cause stiffening of the area to resist stretching when the stomach is full, thus creating a tighter esophageal barrier to reduce the flow of stomach acid and may therefore lead to an improvement in GERD symptoms.

3. **Endoscopic Suturing/ Stapling/ Fastening/ Plication:** Surgical endoscopic treatments (conducted through an endoscope inserted into the esophagus) that use staples, fasteners, or mechanical sutures sewn into the esophagus where it connects to the stomach at or below the gastroesophageal junction to strengthen and lengthen the sphincter in order to create a barrier to reverse the flow of stomach acid. Procedures include transesophageal endoscopic gastroplasty, endoluminal gastric plication (ELGP), endoluminal gastroplication, and transoral incisionless fundoplication (TIF); types of devices include but are not limited to:

   a. Bard® EndoCinch™ Suturing System (Bard Endoscopic Technologies, a subsidiary of C.R. Bard Inc.)

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b. Enteryx™ Procedure Kit (Boston Scientific Corp.)

c. Plicator®/Endoscopic Plicator System (NDO Surgical Inc.)

d. Stomaphyx™ (EndoGastric Solutions, Inc.)

e. Syntheon ARD Plicator (Syntheon)

f. **Transoral Incisionless Fundoplication (TIF) and Associated Devices:** TIF is an incisionless procedure used for the treatment of gastroesophageal reflux disease (GERD). Laparoscopic Nissen fundoplication (rather than endoscopic procedures including TIF) remains the gold standard in surgical interventions for GERD in both adults and children if conservative medical management fails or for those who suffer from complications. TIF differs from a traditional fundoplication procedure because it is performed with a device inserted through the patient’s mouth under visual guidance of an endoscope rather than through laparoscopy or open abdominal incisions. With TIF, the upper curve of the stomach (the fundus) is wrapped around the esophagus much like the Nissen fundoplication. The objective of TIF is to reconfigure tissue to develop a full-thickness gastroesophageal valve from inside the stomach by serosa-to-serosa plications and includes the muscle layers; TIF is 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. TIF is performed using the EsophyX® device (EndoGastric Solutions, Inc.) or the Medigus Ultrasonic Surgical Endostapler system (MUSE™, Medigus Ltd.), as specified below in item (1) and item (2):

(1) TIF with the EsophyX® device (e.g., EsophyX® Z device or EsophyX® with Serofuse™ Fastener device) is 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. The EsophyX® device constructs a valve 3-5 cm long, in a circumferential pattern around the gastroesophageal junction, by deploying non-absorbable polypropylene fasteners through the two layers (esophagus and stomach) under endoscopic vision of the operator. The EsophyX® device includes the following components: A handle that houses the controls, a motorized base with operative channels through which a front-view endoscope can be inserted, an instrument used to turn tissue inward for external suction, a mold to push tissue against the shaft of the device, a helical screw that is advanced into the tissue for retraction, stylets/probes, and a cartridge containing multiple fasteners. Once the device is in place, plication is performed by deploying multiple H-shaped polypropylene fasteners to tighten the circumferential at the gastroesophageal junction. The procedure requires two operators: One handles the device and the other the endoscope.

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TIF with the Medigus Ultrasonic Surgical Endostapler system (MUSE™ system) staples the fundus of the stomach to the esophagus below the diaphragm using multiple sets of metal stitches placed under an ultrasound-guided technique and creates an anterior fundoplication. The MUSE™ system includes a number of components including (but not limited to) the endostapler, camera/video, insertable tube, ultrasonic range finder and various sensors, a pump for insufflation and irrigation, a suction system, power and controls for the illumination (LED), and a cartridge with titanium staples. The device is designed to ensure proper alignment and positioning during stapling for fundoplication. The whole procedure can be done by one operator. In a patient with sliding hiatal hernia, the procedure can be done only if the hernia can be reduced below the diaphragm.

Medical Policy Statement

The Plan considers the use of all endoscopic treatments for gastroesophageal reflux disease (GERD) to be experimental and investigational including but not limited to ANY of the following treatments (or any combination of endoscopic treatments): Endoscopic submucosal implantation/endoscopic injection of bulking agents, transesophageal radiofrequency (also known as the Stretta procedure), and/or endoscopic suturing/stapling/fastening/plication techniques. See the Description of Item or Service section of this policy for a description of endoscopic treatments.

The Plan considers transoral incisionless fundoplication (TIF) to be experimental and investigational when used for the treatment of GERD or for ANY other indication (including but not limited to grade A-B esophagitis and/or symptomatic chronic GERD). TIF can be done using the EsophyX® device (EndoGastric Solutions) or the Medigus Ultrasonic Surgical Endostapler system (MUSE™, Medigus Ltd.).

Limitations

The Plan considers the use of all endoscopic treatments for gastroesophageal reflux disease (GERD) to be experimental and investigational including but not limited to ANY of the following treatments (or any combination of endoscopic treatments): Endoscopic submucosal implantation/endoscopic injection of bulking agents, transesophageal radiofrequency (also known as the Stretta procedure), and/or endoscopic suturing/stapling/fastening/plication techniques. See the Description of Item or Service section of this policy for a description of endoscopic treatments and a list of products that may be used with these techniques.

The Plan considers transoral incisionless fundoplication (TIF) to be experimental and investigational when used for the treatment of GERD or for any other indication (including but not limited to grade A-B esophagitis and/or symptomatic chronic GERD). TIF can be done using the EsophyX® device (EndoGastric Solutions) or the Medigus Ultrasonic Surgical Endostapler system (MUSE™, Medigus Ltd.).
**Definition**

**Fundoplication:** The upper curve of the stomach (the fundus) is wrapped around the esophagus and sewn into place so that the lower portion of the esophagus passes through a small tunnel of stomach muscle. This surgery strengthens the valve between the esophagus and stomach (lower esophageal sphincter), which stops acid from backing up into the esophagus as easily. Fundoplication may be done as an open abdominal surgery, laparoscopically, or as an endoscopic procedure (i.e., transoral incisionless fundoplication [TIF] with the EsophyX® device or TIF with the Medigus Ultrasonic Surgical Endostapler system [MUSE™ system]). Laparoscopic Nissen fundoplication remains the gold standard in surgical interventions for GERD in both adults and children if conservative medical management fails or for those who suffer from complications.

**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. Below are 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
3. **Non-Erosive Esophagitis (NERD):** Inflammation of the esophagus without esophageal injury.

**Gastroplication:** A surgical procedure for reducing of the size of the stomach by suturing a fold in the stomach wall.

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

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

<table>
<thead>
<tr>
<th>ICD-10 Diagnosis Codes</th>
<th>Description: Diagnosis Codes for Gastroesophageal Reflux Disease (GERD)</th>
</tr>
</thead>
<tbody>
<tr>
<td>K21.0 – K21.9</td>
<td>Gastro-esophageal reflux disease</td>
</tr>
<tr>
<td>R12</td>
<td>Heartburn</td>
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</table>

<table>
<thead>
<tr>
<th>CPT Codes</th>
<th>Description: Services Considered Experimental and Investigational for the Treatment of Gastroesophageal Reflux Disease (GERD)</th>
</tr>
</thead>
<tbody>
<tr>
<td>43192</td>
<td>Esophagoscopy, rigid, transoral; with directed submucosal injections(s), any substance</td>
</tr>
</tbody>
</table>

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<table>
<thead>
<tr>
<th>CPT Code</th>
<th>Description: Code Considered Experimental and Investigational for the Treatment of Gastroesophageal Reflux Disease (GERD) or Any Other Indication</th>
</tr>
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<tbody>
<tr>
<td>43210</td>
<td>Esophagogastroduodenoscopy, flexible, transoral; with esophagogastric fundoplasty, partial or complete, includes duodenoscopy when performed</td>
</tr>
</tbody>
</table>

Plan notes:
1. The Plan considers transoral incisionless fundoplication (TIF) to be experimental and investigational when used for the treatment of gastroesophageal reflux disease (GERD) or for any other indication (and all diagnoses).
2. This code is NOT covered (with TIF listed as a benefit exclusion) for the Well Sense Health Plan products (i.e., New Hampshire Medicaid and NH Health Protection Program).

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. According to the American College of Gastroenterology, “the diagnosis of GERD is made using some combination of symptom presentation, objective testing with endoscopy, ambulatory reflux monitoring, and response to antisecretory therapy.”

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 (PPI); these medications can lose their effectiveness over time and require progressively higher dosing.

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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 may or may not be associated with serious complications such as esophagitis, esophageal ulceration or stricture, and/or 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. 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. Esophageal manometry is a test that may be used to identify a weak LES and diagnose GERD. According to CMS NCD 100.4, this test is covered under Medicare where it is determined to be reasonable and necessary for the individual patient; the major use of esophageal manometry is to measure pressure within the esophagus to assist in the diagnosis of esophageal pathology and is mostly used in difficult diagnostic cases and as an adjunct to X-rays and direct visualization of the esophagus (endoscopy) through the fiberscope. Plan guidelines for esophageal manometry are NOT included in this Plan policy; see the Plan’s Code Lookup Tool (sorted by applicable, industry-standard CPT or HCPCS coding for the specified service) and the Prior Authorization/Notification Requirements Matrix (categorized by service type) available at www.bmchp.org for BMC HealthNet Plan members (including the Senior Care Options members) and at www.wellsense.org for Well Sense Health Plan members.

Laparoscopic Nissen fundoplication remains the gold standard in surgical interventions for GERD in both adults and children if conservative medical management fails or for those who suffer from complications. The endoscopic approach to treating GERD has been proposed by a number of devices and unique procedures as an alternative to laparoscopic fundoplication. Several endoscopic techniques have been introduced for the treatment of GERD that include endoscopic submucosal implantation/endoscopic injection of bulking agents, transesophageal radiofrequency (also known as the Stretta procedure), and endoscopic suturing/stapling/fastening/plication techniques. These interventions are proposed to improve the function of the LES, with the objective of eliminating symptoms, healing esophagitis, preventing recurrence of symptoms or progression of disease, and reducing the need for lifelong pharmacological therapy. The esophagus can be examined endoscopically via either a transoral approach or a transnasal approach; a transoral esophagoscopy is passed along the dorsal surface of the tongue and engages the gag reflex and a transnasal esophagoscopy uses an ultra-thin-caliber endoscope that is passed via a topically anesthetized nasal
cavity. The endoscopic treatments for GERD are done on an outpatient basis and generally considered safe based on small studies with short-term follow up reported in the peer reviewed medical literature. Potentially serious complications have been described including mucosal tears of the esophagus and aspiration pneumonia. Other complications include pharyngitis, vomiting, abdominal pain, chest pain, hypoxia, gastric bleeding, bloating, and suture perforation.

A more recent procedure used for the treatment of GERD is the transoral incisionless fundoplication (TIF). TIF differs from a traditional fundoplication procedure because it is performed through the patient’s mouth under visual guidance of an endoscope rather than through laparoscopy or open abdominal incisions. TIF creates a wrap of stomach around the end of the esophagus much like the Nissen fundoplication. The TIF procedure does not require an incision; the device is inserted through the patient’s mouth under visual guidance of an endoscope to reconfigure the tissue/valve between the esophagus and fundus of the stomach (from inside the stomach with plications) to stop acid from backing up into the esophagus as easily. TIF can be done using the EsophyX® device (EndoGastric Solutions) or the Medigus Ultrasonic Surgical Endostapler system (MUSE™, Medigus Ltd.). 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.

Published data regarding the safety and efficacy of the plication/suturing, radiofrequency techniques, and the implantation of bulking agents are limited to small, uncontrolled clinical trials for each technique and are insufficient to prove that these techniques are safe and effective for treatment of GERD. Although the studies report symptomatic relief in some patients, the duration of effect is unknown, and no improvement in objective parameters has been established. Additionally, patient selection criteria have not been defined for these procedures, and there have been no direct comparisons with established treatments such as surgery for GERD. Therefore, based on the available evidence in the peer-reviewed literature, endoscopic treatments for GERD are considered investigational and experimental. At the current time, there is insufficient scientific evidence in the peer reviewed medical literature to support the effectiveness of TIF (with any applicable device) when used for the treatment of symptomatic chronic GERD or for any other indication.

At the time of the Plan’s most recent policy review, the Centers for Medicare & Medicaid Services (CMS) national coverage determination (NCD) 100.9 for implantation of anti-gastroesophageal reflux devices states that implantation of this type of device may be considered reasonable and necessary in specific clinical situations where a conventional valvuloplasty procedure is contraindicated. Implantation of an anti-gastroesophageal reflux device is covered for a Medicare beneficiary with documented severe or life-threatening GERD whose condition has been resistant to medical treatment and also has at least one (1) of the following conditions: (1) Esophageal involvement with progressive systemic sclerosis, (2) foreshortening of the esophagus such that insufficient tissue exists to permit a valve reconstruction, (3) poor surgical risk for a valvuloplasty procedure, and/or (4) the Medicare beneficiary has failed previous attempts at surgical treatment with valvuloplasty procedures.

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According to CMS NCD 100.2 for endoscopy, endoscopic procedures are covered by CMS when reasonable and necessary for a Medicare beneficiary and may be used as a diagnostic tool or as a component of a therapeutic procedure. Verify CMS criteria for the requested service(s) in the applicable NCD or local coverage determination (LCD) in effect on the date of the prior authorization request for a Senior Care Options member.

References


Endoscopic Treatments for GERD in the Outpatient Setting (Including Transoral Incisionless Fundoplication)


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U.S. Food and Drug Administration (FDA). Medical Devices. Accessed at: [http://www.fda.gov/MedicalDevices/default.htm](http://www.fda.gov/MedicalDevices/default.htm)


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<table>
<thead>
<tr>
<th>Original Approval Date</th>
<th>Original Effective Date* and Version Number</th>
<th>Policy Owner</th>
<th>Original Policy Approved by</th>
</tr>
</thead>
<tbody>
<tr>
<td>Regulatory Approval: N/A</td>
<td>10/01/06 Version 1</td>
<td>Medical Policy Manager as Chair of Medical Policy, Criteria, and Technology Assessment Committee (MPCTAC)</td>
<td>Quality and Clinical Management Committee (Q&amp;CMC)</td>
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*Effective Date for the BMC HealthNet Plan Commercial Product(s): 01/01/12
*Effective Date for the Well Sense Health Plan New Hampshire Medicaid Product(s): 01/01/13
*Effective Date for the Senior Care Options Product(s): 01/01/16

Policy formerly titled Endoscopic Treatments for GERD in the Outpatient Setting until 10/31/16. As of 11/01/16 the policy title has been changed to Endoscopic Treatments for GERD in the Outpatient Setting (Including Transoral Incisionless Fundoplication).

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>
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<tbody>
<tr>
<td>07/11/07</td>
<td>Updated template and references. Added coding.</td>
<td>Version 2</td>
<td>07/11/07: MPCTAC 07/24/07: Utilization Management Committee (UMC) 08/13/07: QIC</td>
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<td>07/08/08</td>
<td>Added additional devices and updated references.</td>
<td>Version 3</td>
<td>07/08/08: MPCTAC 07/22/08: UMC 08/13/08: QIC</td>
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<tr>
<td>06/01/10</td>
<td>Updated references and devices for plication. No criteria changes.</td>
<td>Version 5</td>
<td>06/30/10: MPCTAC 07/28/10: QIC</td>
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<tr>
<td>07/01/11</td>
<td>Updated references.</td>
<td>Version 6</td>
<td>08/17/11: MPCTAC</td>
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### Policy Revisions History

<table>
<thead>
<tr>
<th>Date</th>
<th>Description</th>
<th>Version</th>
<th>09/28/11: QIC</th>
<th>08/03/12: MPCTAC 09/05/12: QIC</th>
<th>10/17/12: MPCTAC 11/28/12: QIC</th>
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<tr>
<td>07/29/12</td>
<td>Off cycle review for Well Sense Health Plan, revised Summary statement, revised Medical Policy Statement. Review of entire policy conducted.</td>
<td>Version 7</td>
<td>08/03/12: MPCTAC 09/05/12: QIC</td>
<td>10/17/12: MPCTAC 11/28/12: QIC</td>
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<tr>
<td>10/01/12</td>
<td>Review for effective date 12/01/12. Revised Summary section and Medical Policy Statement section, referenced <em>Experimental and Investigational Treatment</em> policy and <em>Transoral Incisionless Fundoplication (TIF) with the EsophyX System for Gastroesophageal Reflux Disease</em>. policy, updated language in introductory paragraph of Applicable Coding section, updated references.</td>
<td>12/01/12</td>
<td>08/14/13: MPCTAC (electronic vote) 08/15/13: QIC</td>
<td>10/17/12: MPCTAC 11/28/12: QIC</td>
<td></td>
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<td>08/14/15 and 08/15/13</td>
<td>Off cycle review for Well Sense Health Plan and merged policy format. Incorporate policy revisions dated 10/01/12 (as specified above) for the Well Sense Health Plan product; these policy revisions were approved by MPCTAC on 10/17/12 and QIC on 11/28/12 for applicable Plan products. Review of entire policy conducted.</td>
<td>Version 9</td>
<td>08/14/13: MPCTAC (electronic vote) 08/15/13: QIC</td>
<td>10/17/12: MPCTAC 11/28/12: QIC</td>
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<td>08/21/13</td>
<td>Review for effective date 10/01/13. Revised Summary and updated references.</td>
<td>10/01/13</td>
<td>08/21/13: MPCTAC 09/19/13: QIC</td>
<td>10/17/14: MPCTAC 10/08/14: QIC</td>
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<tr>
<td>09/01/14</td>
<td>Review for effective date 01/01/15. Updated Description of Item or Service, Clinical Background Information, and References sections. Added CPT code 43192 as an applicable code. Added ICD9 and ICD10 diagnosis codes for GERD, since the services specified in the applicable CPT codes are considered experimental and investigational when used for the treatment of GERD.</td>
<td>01/01/15</td>
<td>09/17/14: MPCTAC 10/08/14: QIC</td>
<td>10/17/14: MPCTAC 10/08/14: QIC</td>
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<tr>
<td>09/01/15</td>
<td>Review for effective date 11/01/15. Updated template, including the removal of Commonwealth Care, Commonwealth Choice, and Employer.</td>
<td>11/01/15</td>
<td>09/16/15: MPCTAC 10/14/15: QIC</td>
<td>10/17/14: MPCTAC 10/08/14: QIC</td>
<td></td>
</tr>
</tbody>
</table>

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*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.*

17 of 19
## Policy Revisions History

<table>
<thead>
<tr>
<th>Date</th>
<th>Description</th>
<th>Effective Date</th>
<th>Reviewers</th>
</tr>
</thead>
<tbody>
<tr>
<td>11/25/15</td>
<td>Choice because the products are no longer available. Updated references.</td>
<td>01/01/16</td>
<td>11/25/15: MPCTAC (electronic vote) 12/09/15: QIC</td>
</tr>
<tr>
<td>09/01/16</td>
<td>Review for effective date 01/01/16. Revised language in the Applicable Coding section.</td>
<td>11/01/16</td>
<td>09/21/16: MPCTAC 10/12/16: QIC</td>
</tr>
<tr>
<td>09/01/17</td>
<td>Review for effective date 11/01/16. Revised policy title. Updated Summary, Description of Item or Service, Definitions, Clinical Background Information, References, and References to Applicable Laws and Regulations sections. Administrative changes made to the Medical Policy Statement and Limitations sections. Added transoral incisionless fundoplication to the list services included in this policy for all Plan products. As of 10/31/16, retired the <em>Transoral Incisionless Fundoplication (TIF)</em> for <em>Gastroesophageal Reflux Disease (GERD)</em> medical policy, policy number OCA 3.4610 (with retired policy formerly applicable for BMCHP products only). Moved the applicable code for TIF (with no code changes) and criteria for TIF (with no criteria revisions) to this policy and continue to list TIF as an experimental and investigational service. Removed ICD-9 diagnosis codes because the use of these codes is no longer considered industry standard.</td>
<td>10/01/17</td>
<td>09/201/17: MPCTAC</td>
</tr>
</tbody>
</table>

### Last Review Date

09/01/17
Next Review Date

09/01/18

Authorizing Entity

MPCTAC

Other Applicable Policies

Medical Policy - Experimental and Investigational Treatment, policy number OCA 3.12

Reference to Applicable Laws and Regulations


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.

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