Medical Policy

Endoscopic Treatments for GERD in the Outpatient Setting

Policy Number: OCA 3.46
Version Number: 13
Version Effective Date: 01/01/16

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

The Plan considers all endoscopic treatments 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 policy, Experimental and Investigational Treatment (policy number OCA 3.12), for the product-specific definitions of experimental or investigational treatment. See the Plan’s policy, Transoral Incisionless Fundoplication (TIF) with the EsophyX System for Gastroesophageal Reflux Disease (GERD), policy number OCA 3.461, for the Plan’s medical guidelines for the treatment of GERD with this procedure.
Description of Item or Service

Endoscopic Treatments for GERD: Minimally invasive outpatient treatments that alter the structure at the gastroesophageal junction to prevent reflux of the gastric contents. Types of endoscopic treatments include but are not limited to:

1. **Bulking Injection:** These techniques use bulking agents such as Polymethylmethacrylate (PMMA) or Plexiglas microspheres that are injected into the lower esophageal lining. The materials implant into the submucosa for bulking of the tissues which supposedly 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. **Plication/Suturing:** Also known as transesophageal endoscopic gastroplasty or endoluminal gastroplication, these endoscopic treatments use mechanical suturing techniques at or below the gastroesophageal junction to strengthen and lengthen the sphincter in order to create a barrier for the reverse flow of acid. Examples of gastroplication devices include but are not limited to:
   a. Bard® EndoCinch™ Suturing System (Bard Endoscopic Technologies, a subsidiary of C.R. Bard Inc.)
   b. Endoscopic Plicator System
   c. Enteryx™ Procedure Kit (Boston Scientific Corp.)
   d. Plicator® (NDO Surgical Inc.)
   e. Stomaphyx™
   f. Syntheon ARD Plicator

3. **Radiofrequency:** Also known as the Stretta procedure (Curon Medical Inc.), this endoscopic treatment delivers high frequency thermal energy to the lower esophageal sphincter (LES). This treatment is proposed to cause stiffening of the area to resist stretching when the stomach is full, thus creating a barrier to reduce the flow of stomach acid.

Medical Policy Statement

The Plan considers the use of all endoscopic treatments for GERD experimental and investigational.
Limitations

This service is considered experimental and investigational.

Definition

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.

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 Stated 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>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>
<tr>
<td>43201</td>
<td>Esophagoscopy, flexible, transoral; with directed submucosal injection(s), any substance</td>
</tr>
<tr>
<td>43236</td>
<td>Esophagogastroduodenoscopy, flexible, transoral; with directed submucosal injection(s), any substance</td>
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</tbody>
</table>
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>ICD-9 Diagnosis Codes</th>
<th>Description: Diagnosis Codes for Gastroesophageal Reflux Disease (GERD)</th>
</tr>
</thead>
<tbody>
<tr>
<td>530.11</td>
<td>Reflux esophagitis</td>
</tr>
<tr>
<td>530.81</td>
<td>Esophageal reflux</td>
</tr>
<tr>
<td>787.1</td>
<td>Heartburn</td>
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</tbody>
</table>

<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>

### 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. 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/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.

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Endoscopic Treatments for GERD in the Outpatient Setting

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Several endoscopic techniques have been introduced for the treatment of GERD that include plication/suturing, radiofrequency, and bulking agents. 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.

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.

References


## Endoscopic Treatments for GERD in the Outpatient Setting

### Plan
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### Regulatory Approval
Regulatory Approval: N/A

### Internal Approval
08/01/06

### Original Approval Date
Original Approval Date: N/A

### Original Effective Date and Version Number
10/01/06

### Policy Owner
Medical Policy Manager as Chair of Medical Policy, Criteria, and Technology Assessment Committee (MPCTAC) and member of Quality Improvement Committee (QIC)

### Approved by
Quality and Clinical Management Committee (Q&CMC)

### Original Approval Date
Original Approval Date: N/A

### Original Effective Date and Version Number
10/01/06 Version 1

### Policy Owner
Medical Policy Manager as Chair of Medical Policy, Criteria, and Technology Assessment Committee (MPCTAC) and member of Quality Improvement Committee (QIC)

### Approved by
Quality and Clinical Management Committee (Q&CMC)

### Internal Approval
08/01/06

### Original Effective Date and Version Number
10/01/06 Version 1

### Policy Owner
Medical Policy Manager as Chair of Medical Policy, Criteria, and Technology Assessment Committee (MPCTAC) and member of Quality Improvement Committee (QIC)

### Approved by
Quality and Clinical Management Committee (Q&CMC)

### 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

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### 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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<tr>
<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 09/28/11: QIC</td>
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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>
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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 Experimental and Investigational Treatment policy and Transoral Incisionless Fundoplication (TIF) with Experimental and Investigational Treatment policy and Transoral Incisionless Fundoplication (TIF) with</td>
<td>12/01/12 Version 8</td>
<td>10/17/12: MPCTAC 11/28/12: QIC</td>
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<table>
<thead>
<tr>
<th>Date</th>
<th>Description</th>
<th>Version</th>
<th>Revisions Date</th>
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<tr>
<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>
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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 Version 10</td>
<td>08/21/13: MPCTAC 09/19/13: 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 Version 11</td>
<td>09/17/14: MPCTAC 10/08/14: QIC</td>
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<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 Choice because the products are no longer available. Updated references.</td>
<td>11/01/15 Version 12</td>
<td>09/16/15: MPCTAC 10/14/15: QIC</td>
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<td>11/25/15</td>
<td>Review for effective date 01/01/16. Revised language in the Applicable Coding section.</td>
<td>01/01/16 Version 13</td>
<td>11/25/15: MPCTAC (electronic vote) 12/09/15: QIC</td>
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## Last Review Date

11/25/15

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**Next Review Date**

09/01/16

**Authorizing Entity**

QIC

**Other Applicable Policies**

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

Medical Policy - *Transoral Incisionless Fundoplication (TIF) with the EsophyX System for Gastroesophageal Reflux Disease*, policy number OCA 3.461

**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.