Transesophageal Endoscopic Therapies for Gastroesophageal Reflux Disease

Policy # 00123
Original Effective Date: 06/24/2002
Current Effective Date: 01/18/2017

Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc. (collectively referred to as the “Company”), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

Services Are Considered Investigational
Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

Based on review of available data, the Company considers endoscopic submucosal implantation of a prosthesis or injection of a bulking agent (e.g., biocompatible liquid polymer, polymethylmethacrylate [PMMA] beads, zirconium oxide spheres) as a treatment of gastroesophageal reflux disease (GERD) to be investigational.*

Background/Overview
Gastroesophageal reflux disease is a common disorder characterized by heartburn and other symptoms related to reflux of stomach acid into the esophagus. Nearly all individuals experience such symptoms at some point in their lives; a smaller number have chronic symptoms and are at risk for complications of GERD. The prevalence of GERD has been estimated to be 10% to 20% in the Western world, with a lower prevalence in Asia.

The pathophysiology of GERD involves excessive exposure to stomach acid, which occurs for several reasons. There can be an incompetent barrier between the esophagus and stomach, either due to dysfunction of the lower esophageal sphincter (LES) or incompetence of the diaphragm. Another mechanism is abnormally slow clearance of stomach acid by the esophagus. In this situation, delayed clearance leads to an increased reservoir of stomach acid and a greater tendency to reflux.

In addition to troubling symptoms, some patients will have more serious disease, which results in complications such as erosive esophagitis, dysphagia, Barrett esophagus, and esophageal carcinoma. Pulmonary complications may result from aspiration of stomach acid into the lungs and can include asthma, pulmonary fibrosis and bronchitis, or symptoms of chronic hoarseness, cough, and sore throat.

Guidelines on the management of GERD emphasize initial medical management. Weight loss, smoking cessation, head of bed elevation, and elimination of food triggers are all recommended in recent practice guidelines. Proton pump inhibitors (PPIs) have been shown to be the most effective medical treatment. In a Cochrane systematic review, PPIs demonstrated superiority to H2-receptor agonists and prokinetics in both network meta-analyses and direct comparisons.

Due in part to the prevalence of GERD, there has been interest in creating a minimally invasive transesophageal therapeutic alternative to chronic medical therapy. Submucosal injection or implantation of a prosthetic or bulking agent to enhance the volume of the lower esophageal sphincter has been investigated.
One bulking agent, pyrolytic carbon-coated zirconium oxide spheres (Durasphere)\textsuperscript{‡}, is being evaluated.

Endoscopic submucosal implantation of polymethylmethacrylate beads into the lower esophageal folds has also been investigated.

**FDA or Other Governmental Regulatory Approval**

**U.S. Food and Drug Administration (FDA)**

Durasphere is a bulking agent approved for treatment of urinary and fecal incontinence. Use of this product for esophageal reflux would be considered off-label use. The website of Carbon Medical Technologies states that Durasphere GR is an investigational device in the United States “intended to treat problems associated with GERD.”

**Centers for Medicare and Medicaid Services (CMS)**

There is no national coverage determination (NCD).

**Rationale/Source**

**Durasphere**

The available evidence for this device consists of one case series. One open-label pilot study of 10 GERD patients injected Durasphere (Carbon Medical Technologies, Saint Paul, MN), a bulking agent approved for treatment of urinary and fecal incontinence, at the gastroesophageal junction. At 12 months, 7 patients (70\%) discontinued all antacid medication completely. No erosion, ulceration, or sloughing of material was noted at any injection site.

**Gatekeeper Reflux Repair System**

The available evidence for this device consists of one RCT. An industry-funded sham-controlled single-blind multicenter study randomized 118 patients into Gatekeeper (n = 75) or sham (n = 43) treatment. An additional 25 patients were treated as lead-ins during the initial training of investigators and included only in the safety analysis. The patients were implanted initially with 4 Gatekeeper prostheses. At 3 months, 44\% of implanted patients received retreatment with up to 4 additional prostheses due to unsatisfactory symptom control. The primary safety end point was reduction in serious device- and procedure-related adverse device effects, compared with a surgical procedure composite complication rate of 15\%. Four serious adverse events were reported (2 perforations, 1 pulmonary infiltrate related to a perforation, and 1 severe chest pain). The primary efficacy end point was reduction in heartburn symptoms using the GERD-HRQL questionnaire. Planned interim analysis after 143 patients were enrolled found that heartburn symptoms and esophageal acid exposure had improved significantly in both the Gatekeeper and sham groups at 6 months, but there was no significant difference between the 2 groups. The study was terminated early due to a lack of efficacy.

**Polymethylmethacrylate Beads**

The available evidence for this device consists of one case series. A 2001 publication on transesophageal submucosal implantation of PMMA beads consisted of a case series of 10 patients with GERD who were either refractory to or dependent on PPIs. While a significant decrease in symptom scores was noted at
post-treatment follow-up (time not specified), the small number of patients and lack of long-term follow-up preclude scientific analysis. No additional studies have been identified evaluating this treatment option.

Summary
The evidence on injection of bulking agents includes 1 RCT that was terminated early due to lack of efficacy and case series. High-quality data from large RCTs are needed to compare bulking procedures with both sham controls and with the currently accepted treatments for GERD (ie, drug therapy, laparoscopic fundoplication). Well-designed trials should use standardized outcome measures to examine both subjective (eg GERD–Health-Related Quality of Life scores) and objective (eg, esophageal acid exposure) effects on health outcomes. The evidence is insufficient to determine the effects of the technology on health outcomes.

References

Policy History
Original Effective Date: 06/24/2002
Current Effective Date: 01/18/2017
06/20/2002 Medical Policy Committee review.
06/24/2002 Managed Care Advisory Council approval.
04/01/2004 Medical Director review
04/20/2004 Medical Policy Committee review. Format revision. No substance change to policy.
04/26/2004 Managed Care Advisory Council approval
04/05/2006 Medical Director review
04/19/2006 Medical Policy Committee review. Format revision, including addition of FDA and or other governmental regulatory approval and rationale/source. Coverage eligibility unchanged.
04/02/2008 Medical Director review
04/16/2008 Medical Policy Committee approval. No change to coverage eligibility.
04/02/2009 Medical Director review
04/15/2009 Medical Policy Committee approval. No change to coverage eligibility. Title changed to match BCBSA.
04/08/2010 Medical Policy Committee approval
04/21/2010 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
04/07/2011 Medical Policy Committee review
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04/12/2012 Medical Policy Committee review
04/25/2012 Medical Policy Implementation Committee approval. Added NDO Plicator and EsophyX procedures as examples of transesophageal endoscopic gastroplasty. Investigational statements were combined on biocompatible polymer and PMMA beads as bulking agents.

04/04/2013 Medical Policy Committee review
04/24/2013 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
04/03/2014 Medical Policy Committee review
04/23/2014 Medical Policy Implementation Committee approval. Removed the second Investigational statement regarding transesophageal radiofrequency to create thermal lesions of the gastrointestinal junction (i.e., the Stretta procedure) as a treatment of GERD.

04/02/2015 Medical Policy Committee approval
04/20/2015 Medical Policy Implementation Committee approval. Coverage eligibility unchanged. Updated rationale and references.
08/03/2015 Coding update: ICD10 Diagnosis code section added; ICD9 Procedure code section removed.
10/01/2015 Coding update
01/01/2016 Coding update
04/07/2016 Medical Policy Committee approval
04/20/2016 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
01/01/2017 Coding update: Removing ICD-9 Diagnosis Codes
01/05/2017 Medical Policy Committee approval
01/18/2017 Medical Policy Implementation Committee approval. Removed investigational statement on transesophageal endoscopic gastroplasty (EndoCinch, NDO Plicator, or EsophyX). Removed transesophageal endoscopic gastroplasty from the policy.

05/01/2017 Coding update
Next Scheduled Review Date: 01/2018

Coding
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Codes used to identify services associated with this policy may include (but may not be limited to) the following:

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*Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. FDA and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or

B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:

1. Consultation with the Blue Cross and Blue Shield Association technology assessment program (TEC) or other nonaffiliated technology evaluation center(s);
2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
3. Reference to federal regulations.

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