Health Net

National Medical Policy

Subject: **Gastroesophogeal Reflux Disease (GERD), Transendoscopic Therapies for**

Policy Number: **NMP140**

Effective Date*: **April 2004**

Updated: **April 2006, January 2007, February 2008, February 2009**

This National Medical Policy is subject to the terms in the IMPORTANT NOTICE at the end of this document

Current Policy Statement (Update February 2009 - A Medline search failed to reveal any studies that would cause Health Net, Inc. to change its current position)

Health Net, Inc. considers **any** of the following investigational and therefore **not** medically necessary for the management of gastroesophogeal reflux disorder (GERD) because they have not been proven to be an effective treatment option. These procedures will continue to be investigational as long as the long-term efficacy remains uncertain.

1. Transesophageal endoscopic gastroplasty (i.e., the Endocinch procedure, Esophyx EndoLuminal Fundoplication System, Stomaphyx, NDO Surgical Endoscopic Plication System);
2. Transesophageal radiofrequency to create submucosal thermal lesion of the gastroesophageal junction (i.e., Stretta procedure);
3. Endoscopic submucosal implantation of a biocompatible polymer (i.e., Enteryx, Gatekeeper).

Codes Related To This Policy

ICD-9 Codes

530.11	Reflux esophagitis

CPT Codes

43257	Upper gastrointestinal endoscopy including esophagus, stomach, and either the duodenum and/or jejunum as appropriate; with delivery of thermal energy to the muscle of lower esophageal sphincter and/or gastric cardia, for treatment of gastroesophageal reflux disease

0008T	Upper gastrointestinal endoscopy including esophagus, stomach, and either the duodenum and/or jejunum as appropriate, with suturing of the esophagogastric junction (deleted 12/31/06)
0133T	Upper gastrointestinal endoscopy, including esophagus, stomach, and either the duodenum and/or jejunum as appropriate, with injection of implant material into and along the muscle of the lower esophageal sphincter (e.g., for treatment of gastroesophageal reflux disease) (deleted 12/31/07)

HCPCS Codes

C9724	Endoscopic full-thickness placation in the gastric cardia using endoscopic placation system (EPS); includes endoscopy

Scientific Rationale – Update February 2009

Endoscopic or endoluminal procedures for treating GERD can be divided into three main approaches: endoscopic application of radiofrequency delivery thermal energy into the lower esophageal sphincter (LES), suturing devices for the LES that pleat or plicate the upper stomach, and injection or implantation of biopolymers into the gastroesophageal junction. Results have been inconsistent with regard to symptom relief, proton pump inhibitors (PPI) use, and effects on 24-hour pH results and the long-term efficacy is still being defined.

Devices FDA approved and currently available at this time for treating GERD, include EndoCinch (Bard, Davol Inc.), Stretta (Curon Medical Inc.) and Esophyx EndoLuminal Fundoplication (ELF) System (EndoGastric Solutions), Stomaphx (EndoGastric Solutions) and the Plicator (NDO Surgical Inc). Several other devices were removed from the marketplace or terminated from clinical trials due to issues of safety or efficacy [Enteryx (Boston Scientific Inc.), Gatekeeper (Medtronic Inc.), and the Wilson-Cook ESD (Cook Medical Inc.)]

Rothstein (2008) reported endoscopic therapies to treat GERD appear to improve reflux symptoms for the majority of treated patients for a short while, however, durability has been variable among the various treatments, and there have been safety issues with some of the therapies. Although symptom improvement has been universally shown in short-term follow-up, there has been variable outcome for reduced need of antisecretory medications and pH studies show normalization of the distal esophageal acid exposure for only the minority of treated patients. Patients with significant reflux esophagitis or Barrett esophagus are not typically candidates for this antireflux intervention. He notes that except for the NDO Plicator, in sham-controlled studies, there have been no significant differences between treated and sham-treated individuals for ability to discontinue medications or normalize pH.

Torquati and Richards (2007) conducted an evidence-based review of the literature of FDA-approved modalities of endoluminal treatment of GERD. Sixteen studies met the inclusion criteria, representing 787 patients. The authors reported “The methodological quality of most of the included studies was average; four studies were grade 1b (individual randomized trial), 10 were grade 2b (individual cohort

study), and two were grade 3b (individual case-control study) There is grade 1b and 2b evidence demonstrating the EndoCinch plication is effective in reducing GERD symptoms at short-term follow up. However, in the majority of the studies analyzed, the procedure does not significantly reduce the acid exposure in the distal esophagus. The majority of the studies with long-term outcome showed disappointing outcomes, probably due to suture loss in the majority of patients. There is grade 1b and 2b evidence demonstrating that the Stretta procedure is effective in reducing GERD symptoms at short- and mid-term follow up. However, in the majority of the studies analyzed, the procedure did not reduce significantly the acid exposure in the distal esophagus. There is grade 1b and 2b evidence demonstrating that full-thickness plication is effective in reducing GERD symptoms, and acid exposure in the distal esophagus".

Fry et al (2007) also performed a systematic review of endoluminal therapy for GERD. 43 studies, including four randomized, sham-controlled trials that met the inclusion criteria. The primary end point in most studies was the reduction of the use of proton pump inhibitors (PPIs) by more than 50%. The author reported the majority of studies suggested the efficacy of endoluminal therapies for the control of symptoms in GERD. In the sham-controlled studies, the effect of placebo was as high as 50%. Most studies were small feasibility studies, with follow-ups of less than 1 year. No study compared endoscopic techniques with other established treatment options such as PPIs. All endoscopic therapies were associated with a small but important percentage of mild to severe complications, which included perforation, abscess and death. The authors concluded the data from most of the short-term follow-up and the few sham-controlled studies demonstrate that subgroups of patients experienced improvement or resolution of typical GERD symptoms and decreased PPI usage. They further noted that there lacks scientific and clinical data on safety, efficacy and durability to support the use of endoluminal therapies for GERD in routine clinical practice.

In a single-center, double-blind, randomised, sham-controlled trial of endoscopic gastroplication by the Endocinch suturing system, Schwartz et al (2007), investigated 60 patients with GERD randomized to three endoscopic gastroplications (n = 20), a sham procedure (n = 20) or observation (n = 20). After 3 months, open-label active treatment was offered to all patients. The investigators reported at 3 months, the percentage of patients who had reduced drug use by > or =50% was greater in the active treatment group (65%) than in the sham (25%) or observation groups (0%). Symptoms (heartburn and to a lesser extent regurgitation) improved more in the active group than in the sham group. Three Short Form-20 quality of life subscales (role function, general health and bodily pain perception) improved in the active group versus sham. Esophageal acid exposure was modestly decreased after active treatment, but not significantly greater than after the sham procedure. The active treatment effects on PPI use, symptoms and quality of life persisted after 6 and 12 months of open-label follow-up (n = 41), but 29% of patients were retreated in this period. No serious adverse events occurred.

Montgomery et al (2006) investigated forty-six otherwise healthy individuals with GERD treated with proton-pump inhibitors (PPIs), randomized to the EndoCinch plication technique or a sham procedure. Reflux-specific symptoms and use of PPIs (total intake as well as number of patients not taking PPIs) improved in both groups at 6 weeks and at 3 and 12 months post-procedure with an increased improvement in the treatment group at 3 months compared to controls. There were no inter- or intra-group differences in endoscopic findings, esophageal manometry or acid

exposure before or at 3 or 12 months post-procedure. Gastro-esophageal endoscopy showed that 71% and 67% of sutures remained at 3 and 12 months, respectively. The investigator reported that some short-term effects were achieved, however, it was found that there were no differences between the treatment and control groups after 12 months and a lack of reduction of esophageal acid exposure. As a result, they did not recommend the EndoCinch plication technique for use in clinical practice. They suggested that the lack of long-term effects is primarily due to detachment of the sutures.

NDO Plicator

The NDO Surgical Endoscopic Plication System (EPS), by NDO Surgical Inc. (NDO Plicator) creates a full-thickness plication in the anterior cardia, employing a small-caliber (6 mm) pediatric videogastroscope passed through its core to visualize the procedure. The 15 mm outer diameter instrument is passed on a guide wire into the stomach and both the Plicator and the gastroscope are retroflexed to view the gastroesophageal junction. As the two arms of the instrument are opened, a "corkscrew" tissue grasper is advanced into the muscle layer of the anterior cardia within 1 cm of the gastroesophageal junction and this engaged tissue is retracted into the separated arms of the Plicator. The arms are closed together and a single transmural pledgeted suture implant is deployed.

Birk et al (2008) evaluated the safety and efficacy of the Plicator procedure in an open-label, prospective multicenter trial. Patients with symptomatic GERD completed a series of questionnaires at baseline to assess GERD symptoms, heartburn/regurgitation scores, antisecretory medication use, and treatment satisfaction. All the patients then underwent the Plicator procedure with placement of a single transmural pledgeted suture in the anterior gastric cardia. The patients were reevaluated at 12 months after placation. The 12 months follow-up assessment was completed by 81 patients. Effects seen 12 months after placation included improved GERD quality-of-life scores, reduced GERD symptoms and medication use, and yielded higher treatment satisfaction than with the use of chronic antisecretory therapy.

Stomaphyx

In March 2007, the FDA granted 510(k) premarketing clearance to the StomaphyX (EndoGastric Solutions, Inc.), an endoluminal fastener and delivery system used to tighten esophageal tissue. The FDA clearance indicated that the StomaphyX is substantially equivalent to EndoCinch

Esophyx EndoLuminal Fundoplication System (ELF)

The Esophyx EndoLuminal Fundoplication System (EndoGastric Solutions) device received FDA approval in September 2007. The FDA clearance indicated that the device is substantially equivalent to the StomaphyX and EndoCinch devices. The Esophx system is designed to treat GERD endoscopically via restoration of the angle of His at the gastroesophageal junction. The technique uses suction to grasp tissue at the gastroesophageal junction to push it forward to the stomach. A helical retractor is then used to engage the fundus and manipulate its position to create the correct angle, while fixing the tissue in place by deploying multiple transmural fasteners.

Cadiere et al (2008) evaluated the endoluminal fundoplication (ELF) technique performed transorally using the EsophyX device in nineteen patients with GERD in a prospective, feasibility clinical trial. Inclusion criteria were chronic and symptomatic GERD, proton pump inhibitor (PPI) dependence, and the absence of esophageal motility disorder. Two patients were excluded due to esophageal stricture and a 6 cm hiatal hernia. The median duration of GERD symptoms and PPI use in the remaining 17 patients was 10 and 6 years, respectively. The ELF procedure was designed to partially reconstruct the antireflux barrier through the creation of a valve at the gastroesophageal junction. Adverse events were limited to mild or moderate pharyngeal irritation and epigastric pain, which resolved spontaneously. After 12 months, eighty-one percent of valves retained their tightness. The hiatal hernias present at the baseline remained reduced in 62% of patients. The median GERD-HRQL scores improved by 67% and nine patients (53%) improved their scores by >or=50%. Eighty-two percent of patients were satisfied with the outcome of the procedure, 82% remained completely off PPIs, and 63% had normal pH. The investigator concluded the study demonstrated technical feasibility and safety of the ELF procedure using the EsophyX device. The study also demonstrated maintenance of the anatomical integrity of the ELF valves for 12 months and provided preliminary data on ELF efficacy in reducing the symptoms and medication use associated with GERD. Preclinical testing reports that the EsophyX System is safe, but long-term safety and efficacy studies are still needed.

There are several newer devices under study or in development, including but not limited to, the Syntheon AntiReflux Device (ARD) and the Medigus endoscopy system. The Syntheon ARD delivers a single titanium implant into the cardia of the stomach, creating a serosa-to-serosa apposition and altering the anatomy of the proximal stomach in a fashion similar to that of the NDO device. Unlike the NDO device, the ARD instrument and an endoscope can be passed independently of each other. This permits any upper endoscope to be used, placed alongside the ARD and retroflexed to view the cardia. A catheter-based tissue retractor is passed through the endoscope biopsy channel to pull the proximal stomach into the open arms of the ARD. As the arms close upon the retracted tissue of the distal gastroesophageal junction, the titanium implant is deployed to create a full-thickness "pleat". The Syntheon ARD is currently undergoing FDA review.

The Medigus endoscopy system also known as Medigus SRS combines a miniaturized video camera, a surgical stapler, and ultrasonic sights for alignment in a single instrument. The SRS is designed to perform an anterior fundoplication endoluminally. At this time, this device is not FDA approved and is considered investigational. The device has been used in only a small number of patients in Australia and India. A phase III clinical trial (NCT00734747), to investigate the safety and efficacy of this device, sponsored by Medigus LTD, is currently recruiting participants.

Scientific Rationale – Update January 2007

(2006) A very recent technical review of the American Gastroenterological Association (AGA) Institute on the use of endoscopic therapy for gastroesophageal reflux disease states:

> "Most studies of endoscopic therapy have only limited follow-up information of a relatively small number of patients. Thus, the durability of these technologies beyond 1–2 years remains unclear. Short-term and long-term safety issues are unresolved, but serious adverse events led to the voluntary withdrawal of Enteryx by the

manufacturer in September 2005 and suspension of the Gatekeeper clinical program in late 2005. The economics of all techniques for the patient, practitioner, and society are unknown. While newer devices and improvements in endoscopic antireflux techniques may yield better and more durable treatment outcomes, current data suggest that there are no definite indications for endoscopic therapy for GERD at this time. Both practitioners and patients need to be aware of the limitations in the evidence that exist with these devices at present."

Scientific Rationale - Initial

Gastroesophageal reflux disease (GERD) is a chronic condition that affects between 25% and 35% of the U.S. population. It occurs when gastric acid refluxes into the esophagus at higher than normal limits, causing symptoms with or without associated esophageal mucosal injury or esophagitis. In addition to the typical symptoms (heartburn, regurgitation, dysphagia), abnormal reflux can cause atypical symptoms such as coughing, chest pain, and wheezing as well as damage to the lungs such as pneumonia, asthma, idiopathic pulmonary fibrosis, damage to vocal cords, laryngitis, cancer, otitis media, and tooth enamel decay. The primary complications of GERD include strictures, ulcerations and Barrett's esophagus (progressive replacement of distal eroded squamous mucosa with metaplastic gastric epithelium). Patients with Barrett's esophagus have a greater risk of developing adenocarcinoma of the esophagus, though the overall risk remains low.

The lower esophageal sphincter (LES) plays an important role for preventing reflux. The LES is a ring of muscle that surrounds the distal end of the esophagus where it joins the stomach. This sphincter prevents reflux by contracting and closing off the passage from the esophagus into the stomach. It opens briefly for a few seconds when food or saliva is swallowed to allow passage from the esophagus to the stomach, but closes again.

Abnormalities of the LES have been found in patients with GERD, causing weak contractions or inappropriate relaxation. Both of these situations reduce the ability to prevent reflux. Abnormal relaxations of the LES, called transient LES relaxations, allow reflux to occur more easily usually after meals when the stomach is distended with food. The most recently-described abnormality in patients with GERD is laxity of the LES. Specifically, similar distending pressures open the LES more in patients with GERD than in individuals without GERD.

Patients with GERD should be treated initially with antacids, H2-receptor antagonists, as well as dietary and lifestyle modifications. If no improvement is obtained, proton pump inhibitors or PPI (e.g., lansoprazole and omeprazole) should be tried. For patients with severe, difficult-to-control GERD symptoms or if complications such as recurrent asthma or pneumonia, or strictures of the esophagus from scar tissue are present, surgery may be considered. Laparoscopic surgical techniques such as the Nissan fundoplasty have been successful. Some patients who wish to avoid prolonged medical therapy may opt for laparoscopic surgery.

In 2002, the FDA cleared two devices as less invasive options for the treatment of GERD that is refractory to medical treatment, the Stretta Procedure and the Endocinch System.

Stretta Procedure

The Stretta procedure (Curon Medical Inc., Sunny Vale, CA) is a minimally invasive outpatient endoscopic procedure. Radiofrequency energy is used to create thermal lesions in the lower esophageal sphincter (LES) and gastric cardia. A balloon is inflated and needle electrodes are deployed from a basket surrounding the balloon into the tissue. Each needle tip incorporates a thermocouple, which automatically modulates power output to maintain a desired target (muscle) tissue temperature. Maintaining lesion temperatures below 100ºC minimizes the collateral tissue damage due to vaporization and high impedance values. As these lesions heal, the treated tissue resorbs and shrinks, increasing resistance to reflux. It is believed that the changes that occur immediately, and over time result in a "tighter" LES and a less compliant gastric cardia. Additionally, the interruption of nerve pathways in the LES area is believed to reduce the incidence of inappropriate LES "relaxations", leading to an improvement in GERD symptoms.

Review of the medical literature indicates that studies of the Stretta procedure have largely been uncontrolled and have not involved direct comparison with other established medical or surgical therapies. Reported complications are uncommon (.83% per 1200 procedures) but severe, including dysphagia, chest pain, fever, mucosal injury and perforation. Long-term results are not yet available and, therefore, this procedure is considered experimental in nature.

Endocinch Procedure

Endoluminal gastroplication works by creating plications, or pleats, at the lower esophageal sphincter (LES). Endocinch (Bard, Billerica, MA) received approval from the United States Food and Drug Administration in March 2000. Patients are selected for the treatment of GERD if they have no Barrett's epithelium and if any associated hiatal hernia is less than 2 cm in diameter. The EndoCinch System resembles miniature sewing machine and is attached to the end of a standard, flexible endoscope. The physician places two stitches tied together to create a pleat near the LES, altering it to reduce the backflow of acid from the stomach up through the esophagus. Stitches may be placed below the cardioesophageal junction in a linear or circumferential configuration.

Two multicenter studies have been reported in the medical literature indicating that there was significant improvement in heartburn scores, regurgitation, increase in LES pressure and decrease in the pH of gastric secretions. Reported adverse events associated with the EndoCinch include pharyngitis, vomiting, abdominal/chest pain, mucosal tear, hypoxia, and clinically significant bleeding. The authors note that long term studies and guidelines for patient selection are needed to ensure that these initial promising results are sustained, and that, over time, patients do not need to be retreated with PPIs.

Enteryx

Enteryx (Boston Scientific Corp, Natick, MA) is a chemically inert, non-carcinogenic, hypoallergenic, non-antigenic radiopaque compound that is available in a liquid organic state but becomes solid on hydration (or placement in tissue). It is an injectable solution containing 8 percent ethylene vinyl alcohol copolymer (EVOH) dissolved in dimethyl sulfoxide (DMSO). Enteryx has been used in the treatment of arteriovenous malformations, peripheral vascular disease, and hypervascular head and neck cancers. For treatment of GERD, it is injected into the LES under fluoroscopic and endoscopic guidance and solidifies into a sponge-like permanent

implant and prevents or reduces gastric acid reflux into the esophagus.

Enteryx was granted premarket approval by the FDA on April 22, 2003, based in the recommendation by the Gastroenterology and Urology Devices Advisory Panel of the FDA. Premarket approval included 10 conditions and a post-market study to be performed as a placebo-sham controlled trial that also examined the effects of re-treatment Enteryx.

Reported adverse events associated with injection bulking agents include chest pain, dysphagia, fever, bleeding, and bloating. Given the small number of patients studied and the lack of a controlled trial, there are inadequate data to determine whether or not injection of a polymer is at least as good as the established alternative of medical therapy.

Review History

April 2004	Medical Advisory Council initial approval
April 2006	Update - no changes
January 2007	Update - no changes
March 2007	Code updates
February 2008	Update – no changes. Coding updates
February 2009	Updated scientific rationale with information regarding the various devices available for treatment, however, no change to policy statement – treatment remains investigational.

Patient Education Websites

English

1. MedlinePlus. Gastroesophageal Reflux Disease (GERD). Available at: http://www.clevelandclinic.org/health/health-info/docs/1600/1697.asp?index=7042
2. MedlinePlus. Heartburn, Gastroesophageal Reflux (GER), and Gastroesophageal Reflux Disease (GERD). Available at: http://digestive.niddk.nih.gov/ddiseases/pubs/gerd/

Spanish

1. MedlinePlus. Temas y publicaciones de la A a la Z. Acesso en: http://digestive.niddk.nih.gov/spanish/indexsp.asp
2. MedlinePlus. Reflujo gastroesofágico. Acesso en: http://www.nlm.nih.gov/medlineplus/spanish/gerd.html

This policy is based on the following evidence-based guideline:

1. Falk GW, Fennerty MB, Rothstein RI. American Gastroenterological Association (AGA) Institute technical review on the use of endoscopic therapy for gastroesophageal reflux disease. Gastroenterology. Oct 2006;131:1315–1336. Available at: http://www.gastrojournal.org/article/PIIS0016508506017586/fulltext?refuid=PIIS0016508506017574
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40. U.S. FDA 510(k) Summary. StomaphyX endoluminal fastener and delivery System. EndoGastric Solutions, Inc. Feb. 2007. Available at: http://www.fda.gov/cdrh/pdf6/K062875.pdf
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Important Notice

General Purpose.
Health Net's National Medical Policies (the "Policies") are developed to assist Health Net in administering plan benefits and determining whether a particular procedure, drug, service or supply is medically necessary. The Policies are based upon a review of the available clinical information including clinical outcome studies in the peer-reviewed published medical literature, regulatory status of the drug or device, evidence-based guidelines of governmental bodies, and evidence-based guidelines and positions of select national health professional organizations. Coverage determinations are made on a case-by-case basis and are subject to all of the terms, conditions, limitations, and exclusions of the member's contract, including medical necessity requirements. Health Net may use the Policies to determine whether under the facts and circumstances of a particular case, the proposed procedure, drug, service or supply is medically necessary. The conclusion that a procedure, drug, service or supply is medically necessary does not constitute coverage. The member's contract defines which procedure, drug, service or supply is covered, excluded, limited, or subject to dollar caps.

Policy Effective Date and Defined Terms.
The date of posting is not the effective date of the Policy. The Policy is effective as of the date determined by Health Net. All policies are subject to applicable legal and regulatory mandates and requirements for prior notification. If there is a discrepancy between the policy effective date and legal mandates and regulatory requirements, the requirements of law and regulation shall govern. * In some states, new or revised policies require prior notice or posting on the website before a policy is deemed effective. For information regarding the effective dates of Policies, contact your provider representative. The Policies do not include definitions. All terms are defined by Health Net. For information regarding the definitions of terms used in the Policies, contact your provider representative.

Policy Amendment without Notice.
Health Net reserves the right to amend the Policies without notice to providers or Members. In some states, new or revised policies require prior notice or website posting before an amendment is deemed effective.

No Medical Advice.
The Policies do not constitute medical advice. Health Net does not provide or recommend treatment to members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

No Authorization or Guarantee of Coverage.
The Policies do not constitute authorization or guarantee of coverage of particular procedure, drug, service or supply. Members and providers should refer to the Member contract to determine if exclusions, limitations, and dollar caps apply to a particular procedure, drug, service or supply.

Policy Limitation: Member's Contract Controls Coverage Determinations.

The determination of coverage for a particular procedure, drug, service or supply is not based upon the Policies, but rather is subject to the facts of the individual clinical case, terms and conditions of the member's contract, and requirements of applicable laws and regulations. The contract language contains specific terms and conditions, including pre-existing conditions, limitations, exclusions, benefit maximums, eligibility, and other relevant terms and conditions of coverage. In the event the Member's contract (also known as the benefit contract, coverage document, or evidence of coverage) conflicts with the Policies, the Member's contract shall govern. Coverage decisions are the result of the terms and conditions of the Member's benefit contract. The Policies do not replace or amend the Member's contract. If there is a discrepancy between the Policies and the Member's contract, the Member's contract shall govern.

Policy Limitation: Legal and Regulatory Mandates and Requirements.
The determinations of coverage for a particular procedure, drug, service or supply is subject to applicable legal and regulatory mandates and requirements. If there is a discrepancy between the Policies and legal mandates and regulatory requirements, the requirements of law and regulation shall govern.

Policy Limitations: Medicare and Medicaid.
Policies specifically developed to assist Health Net in administering Medicare or Medicaid plan benefits and determining coverage for a particular procedure, drug, service or supply for Medicare or Medicaid members shall not be construed to apply to any other Health Net plans and members. The Policies shall not be interpreted to limit the benefits afforded Medicare and Medicaid members by law and regulation.