

## Medical Policy Manual

**Topic:** Gastric Reflux Surgery

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**Section:** Surgery

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### IMPORTANT REMINDER

Medical Policies are developed to provide guidance for members and providers regarding coverage in accordance with contract terms. Benefit determinations are based in all cases on the applicable contract language. To the extent there may be any conflict between the Medical Policy and contract language, the contract language takes precedence.

PLEASE NOTE: Contracts exclude from coverage, among other things, services or procedures that are considered investigational or cosmetic. Providers may bill members for services or procedures that are considered investigational or cosmetic. Providers are encouraged to inform members before rendering such services that the members are likely to be financially responsible for the cost of these services.

### DESCRIPTION

Gastroesophageal reflux disease (GERD) is a chronic medical condition, defined as “troublesome symptoms and/or complications” caused by reflux or regurgitation of stomach acid.<sup>[1]</sup> GERD is a common disorder; the proportion of North American adults with GERD (those who report experiencing symptoms such as heartburn or acid reflux at least once a week, or those with a physician diagnosis of GERD) is estimated to be around 19.8-20%.<sup>[2]</sup> GERD has also been associated with extraesophageal symptoms or conditions, such as cough, laryngitis, asthma and pulmonary fibrosis, although a direct causal relationship with GERD has not been established.

Standard treatment of GERD may address lifestyle modifications as appropriate to individual patients such as weight loss, smoking cessation, avoidance of specific foods that may precipitate reflux or heartburn, elevating the head of the bed, and avoiding recumbent positions until 2-3 hours after a meal.<sup>[1]</sup> When these actions are not successful, treatment generally consists of a daily regimen of proton pump inhibitors (PPIs). However, some patients with chronic GERD are unable or unwilling to continue ongoing medical treatment. For these patients, surgical treatment may be considered.

Surgical fundoplication involves wrapping the fundus of the stomach around the lower esophagus in order to create a high pressure zone that reduces gastroesophageal reflux. The fundal wrap can be either total (360 degrees) or partial (<360 degrees). Fundoplication may be performed as an open procedure but is more commonly performed laparoscopically.

## Esophagogastric Fundoplasty With Paraesophageal Hiatal Hernia Repair

In some cases, patients may exhibit a paraesophageal hiatal hernia with symptoms of GERD, requiring hernia repair in conjunction with fundoplication. Paraesophageal hiatal hernias, also known as Type II hiatal hernias, occur when the stomach herniates through the diaphragmatic esophageal hiatus alongside the esophagus. In cases of “true” paraesophageal hiatal hernia, the gastroesophageal junction remains below the hiatus and the stomach rotates in front of the esophagus and herniates into the chest. These cases are rare, representing only 5% of all hiatal hernias compared to the more common Type I or “sliding” type hiatal hernia. Diagnosis of a “true” paraesophageal hiatal hernia is confirmed through endoscopy or imaging studies. Prophylactic surgical treatment of paraesophageal hiatal hernias is common as they account for most of the complications associated with hiatal hernias, including but not limited to obstruction, perforation and strangulation.<sup>[3]</sup>

## Esophagogastric Fundoplasty in Patients with Pulmonary Fibrosis

Idiopathic pulmonary fibrosis (IPF) is a progressive lung disease which is often associated with additional comorbidities (eg, pulmonary hypertension and gastroesophageal reflux) and symptoms (eg, dyspnea, exercise limitation, fatigue, anxiety, mood disturbance, sleep disorders) that negatively affect patients’ lives. GERD is highly prevalent in patients with IPF with up to 50% of patients with asymptomatic disease. Although the pathological significance of GERD in IPF remains uncertain, studies indicate that medical or surgical treatment of GERD may stabilize lung function and increase oxygenation.<sup>[4-7]</sup> It is hypothesized that fundoplication surgery may offer increased benefit over medication treatment by reducing acid as well as microaspirations of the gastric contents in to the lungs.<sup>[4]</sup>

Due to the complexities of IPF, treatment protocols are not rigid or standardized and often require a management approach which is tailored to the patients’ specific conditions and symptoms. Nissen fundoplication surgery is one option which may be considered for treating patients with pulmonary fibrosis with symptomatic or asymptomatic GERD.

Note: this policy does not address transesophageal endoscopic therapies for GERD, which are addressed separately in Surgery Policy No. 110 (see Cross References).

### **MEDICAL POLICY CRITERIA**

#### I. Esophagogastric fundoplasty

Initial esophagogastric fundoplasty may be considered **medically necessary** for the treatment of symptomatic gastroesophageal reflux disease (e.g., heartburn, regurgitation) when all of the following criteria A-C) are met:

- A. Lifestyle Modifications Symptoms are unresponsive to one or more of the following lifestyle modifications as appropriate to the individual patient:
  - 1. Weight loss for overweight or obese patients
  - 2. Avoidance of late meals, specific foods that cause heartburn (coffee, alcohol, chocolate, fatty foods, citrus, carbonated drinks, spicy foods)

3. Avoidance of specific activities that may cause heartburn, such as recumbency within 2-3 hours after a meal
4. Elevation of the head of the bed for patients who develop heartburn or regurgitation when recumbent

AND

B. Medication Therapy

1. A 6-month trial of proton pump inhibitors (PPIs), including at least two different PPIs, is ineffective, contraindicated, or not tolerated.

OR

2. PPIs adequately control symptoms but are continuously required for 12 or more months and surgery is considered an alternative to long term medication use.

AND

C. Diagnostic Confirmation

There is objective documentation of reflux and/or esophagitis via endoscopy. If endoscopy is normal, objective evidence of reflux should include at least one of the following: 24-hour ambulatory esophageal pH monitoring or barium swallow.

II. Esophagogastric fundoplasty with paraesophageal hiatal hernia repair

Initial or repeat esophagogastric fundoplasty with a paraesophageal hiatal hernia repair may be considered medically necessary when all of the following criteria are met:

- A. Criteria I. A-C for esophagogastric fundoplasty above are met,

AND

- B. Documentation of the paraesophageal hiatal hernia is confirmed by imaging or endoscopy study.

III. Esophagogastric fundoplasty with esophageal myotomy

Initial or repeat esophagogastric fundoplasty with esophageal myotomy may be considered medically necessary when all of the following criteria are met:

- A. Criteria I. A-C for esophagogastric fundoplasty above are met,

AND

- B. In conjunction with a medically necessary esophageal myotomy in patients with achalasia.

IV. Repeat esophagogastric fundoplasty

Repeat esophagogastric fundoplasty for a failed previous antireflux procedure may be considered medically necessary when either of the following criteria (A or B) are met:

A. Criteria I. A-C for esophagogastric fundoplasty above are met,

OR

B. Repeat surgery is for a documented mechanical failure of previous antireflux procedure (e.g., obstruction).

V. Esophagogastric fundoplasty may be considered **medically necessary** in patients with pulmonary fibrosis with symptomatic or asymptomatic gastroesophageal reflux disease.

VI. Esophagogastric fundoplasty is considered **not medically necessary** for the treatment of symptomatic gastroesophageal reflux disease (e.g., heartburn, regurgitation) when the criteria above are not met.

## SCIENTIFIC EVIDENCE

In order to determine whether the benefits of surgical fundoplication in patients with chronic GERD outweigh the risks, well-designed randomized controlled trials (RCTs) are necessary, comparing medical therapy (proton pump inhibitors) with surgical fundoplication and reporting on relevant clinical outcomes.

The focus of the following literature review is on systematic reviews, randomized trials published after the systematic reviews, and clinical practice guidelines.

### Literature Appraisal

#### Systematic Reviews

In 2010, The Cochrane Collaboration published a systematic review on medical versus surgical management for GERD in adults.<sup>[8]</sup> Included in the review were all randomized or quasi-randomized controlled trials comparing laparoscopic fundoplication with medical management; nonrandomized studies were excluded. Four trials with a total of 1232 patients were included.<sup>[9-12]</sup> All reported outcomes at one year, with only one reporting outcomes up to three years. There were no studies that followed patients longer than three years.

The authors reported the following findings:

- The included studies were considered to be at medium or low risk of bias, with two studies failing to provide detailed information about whether allocation was concealed (a key factor when evaluating the risk of bias).
- In the surgical treatment group, there were statistically significant improvements in health-related quality-of-life measures in the short- to medium-term (three months and one year after surgery, respectively) compared with medical therapy.

- All studies found that symptoms of heartburn and regurgitation were improved after surgery compared with medical therapy.
- Three studies reported either a higher proportion of surgical participants with dysphagia or more severe postoperative dysphagia.
- With respect to surgical risks, the rate of postoperative complications was low (21/519; 4%). No participants died during the initial admission for surgery; however, one study reported a higher proportion of serious adverse events in surgical compared with medical patients (21% versus 14%). There were no data on late adverse events; the authors cautioned that actual event rates may be under-reported.
- Only one study compared rates of oral, prescribed or over-the-counter medication use and found that 12.5% of surgical participants were taking prescribed PPIs at one year postoperatively compared with 90% of medical participants. The authors noted that surgical participants from other studies could have self-managed persistent symptoms with over-the-counter medications.

Overall, the authors concluded that in the short- to medium-term there is evidence that laparoscopic fundoplication is more effective than medical management. However, they note that surgery carries some risk, and it is uncertain whether the benefits of surgery are sustained in the long term. They note, “Other systematic reviews of randomized controlled trials comparing open versus laparoscopic surgery have suggested that benefits of laparoscopic surgery may not be sustained over time, thus there is a need for longer-term follow-up.”

This systematic review did not address surgical treatment of GERD patients with pulmonary fibrosis.

#### Randomized Controlled Trials (RCTs)

Since publication of the Cochrane review, Anvari and colleagues reported 3-year outcomes from a prospective RCT, the one-year results of which were included in the Cochrane review. Of note, *a priori*, a sample size of 216 was calculated for this study at a statistical significance level of  $\alpha = 0.05$ ; however only 104 participants were ultimately randomized which may have impacted the ability of the study to detect significant changes.

Of the original 104 subjects, 93 were available for the 3-year follow-up assessment. The authors reported the following outcomes:

- Improvement from baseline in GERD symptoms was significant in both the medical treatment and surgical groups. Differences between the two groups were not significant. (Primary outcome)
- Surgical patients experienced a mean of 1.35 more heartburn-free days per week compared with the medical group, a significant difference. (Primary outcome)
- Both groups demonstrated improvements in acid reflux and did not differ significantly in change from baseline. (Secondary outcome)
- The surgical group had significantly better lower esophageal sphincter pressure than the medical group. (Secondary outcome)
- With respect to global symptom control compared with baseline measurements, medically treated patients maintained their control, but the surgical patients demonstrated a statistically significant improvement from baseline. (Secondary outcome)
- Significant improvements in quality of life scores were also seen in the surgical group compared with the medical group. (Secondary outcome)

- 6 (11.8%) patients in the surgical group and 8 (16%) patients in the medical group failed their primary treatment.
- No adverse events were reported in the medical treatment group. In the surgical group:
  - There were no intraoperative complications, major morbidities, or mortality
  - 7 patients experienced minor postoperative complications
  - 4 patients reported dysphagia; 7 reported postprandial bloating at 3 months
  - 2 patients required dilation of the wrap

There were no randomized trials investigating medical vs. surgical treatment of GERD patients with pulmonary fibrosis.

### Nonrandomized Studies: Surgical Treatment of GERD Patients with Pulmonary Fibrosis

Current evidence regarding fundoplication in patients with pulmonary fibrosis (PF) mainly consist of case series<sup>[13,14]</sup> and review articles, which indicated that silent reflux, or asymptomatic GERD, occurs in about a third of PF patients.<sup>[5,7]</sup> Only a single case series was identified regarding the efficacy of reflux surgery in patients with IPF and GERD symptoms who were awaiting lung transplant:

In 2006, Linden and colleagues evaluated Laparoscopic fundoplication in patients with GERD symptoms and end-stage lung disease awaiting transplantation.<sup>[6]</sup> Of 149 patients on the transplant wait list, 19 were identified as having a history of reflux and of those, 14 were diagnosed with IPF. All 14 IPF patients underwent a Nissen fundoplication and were compared to 31 patients with IPF on the transplant list who did not have fundoplication surgery. No perioperative complications or decreases in lung function were reported over a mean 15 month follow-up period. Authors reported that, "patients with idiopathic pulmonary fibrosis treated with fundoplication had stable oxygen requirements, whereas control patients with idiopathic pulmonary fibrosis on the waiting list had a statistically significant deterioration in oxygen requirement."

Overall, the evidence regarding Nissen fundoplication as a treatment of gastrointestinal reflux disease (GERD) in patients with pulmonary fibrosis (PF) is limited; however, treatment of PF is often tailored to treat a patients' specific condition and symptoms. Potential benefits of fundoplication surgery in PF patients include improved oxygenation and reduction of acid and microaspiration into the lungs. Considering no standardized treatment protocol for patients with PF if available, Nissen fundoplication surgery may be considered in patients with symptomatic or asymptomatic GERD to reduce acid reflux and microaspirations to the lungs.

### **Clinical Practice Guidelines**

Two evidence-based clinical practice guidelines address surgical treatment of GERD. These guidelines offer differing recommendations concerning indications for surgery. No evidence clinical practice guidelines were identified which recommend fundoplication surgery as a treatment of GERD in patients with pulmonary fibrosis.

### Society of American Gastrointestinal and Endoscopic Surgeons (SAGES)<sup>[15]</sup>

SAGES guidelines recommend surgical therapy when the diagnosis of reflux is objectively confirmed, in individuals who:

- 1) have failed medical management (inadequate symptom control, severe regurgitation not controlled with acid suppression, or medication side effects)

OR

2) opt for surgery despite successful medical management (due to quality of life considerations, lifelong need for medication intake, expense of medications, etc.)

OR

3) have complications of GERD (e.g., Barrett's esophagus, peptic stricture)

OR

4) have extra-esophageal manifestations (asthma, hoarseness, cough, chest pain, aspiration)

“Surgical therapy for GERD is an equally effective alternative to medical therapy and should be offered to appropriately selected patients by appropriately skilled surgeons (Grade A\*). Surgical therapy effectively addresses the mechanical issues associated with the disease and results in long-term patient satisfaction (Grade A). For surgery to compete with medical treatment, it has to be associated with minimal morbidity and cost.”

*\*Definitions*

- Grade A: “Based on high level (Level I or II), well-performed studies with uniform interpretation and conclusions by the expert panels”
- Level I Evidence: “Evidence from properly conducted randomized, controlled trials
- Level II Evidence: “Evidence from controlled trials without randomization; cohort or case-control studies; multiple time series; dramatic uncontrolled experiments

American Gastroenterological Association (AGA)<sup>[1]</sup>

- “When antireflux surgery and PPI therapy are judged to offer similar efficacy in a patient with an esophageal GERD syndrome, PPI therapy should be recommended as initial therapy because of superior safety.” (Grade A\*\*)
- “When a patient with an esophageal GERD syndrome is responsive to, but intolerant of, acid suppressive therapy, antireflux surgery should be recommended as an alternative.” (Grade A)
- Antireflux surgery is recommended “for patients with an esophageal GERD syndrome with persistent troublesome symptoms, especially troublesome regurgitation, despite PPI therapy. The potential benefits of antireflux surgery should be weighed against the deleterious effect of new symptoms consequent from surgery, particularly dysphagia, flatulence, an inability to belch, and postsurgery bowel symptoms.” (Grade B\*\*)
- “Patients with an extraesophageal GERD syndrome with persistent troublesome symptoms despite PPI therapy should be considered for antireflux surgery. The potential benefits of antireflux surgery should be weighed against the deleterious effect of new symptoms consequent from surgery, particularly dysphagia, flatulence, an inability to belch, and postsurgery bowel symptoms.” (Grade C\*\*)
- The AGA recommends against antireflux surgery (Grade D\*\*):
  - “for patients with an esophageal syndrome with or without tissue damage who are symptomatically well controlled on medical therapy.”
  - “as an antineoplastic measure in patients with Barrett's metaplasia.”

*\*\*Definitions*

- Grade A: “strongly recommended based on good evidence that it improves important health outcomes.”
- Grade B: “recommended with fair evidence that it improves important outcomes”
- Grade C: “balance of benefits and harms is too close to justify a general recommendation”
- Grade D: “recommend against, fair evidence that it is ineffective or harms outweigh benefits”

## Summary

Gastroesophageal reflux disease (GERD) is a chronic medical condition that can be effectively controlled for most patients with lifestyle changes and long-term use of proton pump inhibitors (PPIs). For those patients with chronic GERD who are unable or unwilling to continue ongoing medical treatment, short- to medium-term evidence from published randomized controlled trials indicates that surgery may be as effective or slightly more effective than ongoing medication therapy. Therefore, esophagogastric fundoplasty may be considered medically necessary as a treatment of chronic GERD in select patients. The benefits from surgery should be weighed against potential risks. In addition, it is not known if these benefits are maintained over the long-term.

## REFERENCES

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## CROSS REFERENCES

[Bariatric Surgery](#), Surgery, Policy No. 58

[Transesophageal Endoscopic Therapies for Gastroesophageal Reflux Disease \(GERD\)](#), Surgery, Policy No. 110

[Magnetic Esophageal Ring to Treat Gastroesophageal Reflux Disease \(GERD\)](#), Surgery, Policy No. 190

CODES	NUMBER	DESCRIPTION
CPT	43279	Laparoscopy, surgical, esophagomyotomy (Heller type), with fundoplasty, when performed
	43280	Laparoscopy, surgical, esophagogastric fundoplasty (eg, Nissen, Toupet procedures)
	43281	Laparoscopy, surgical, repair of paraesophageal hernia, includes fundoplasty, when performed; without implantation of mesh
	43282	; with implantation of mesh
	43325	Esophagogastric fundoplasty; with fundic patch (Thal-Nissen procedure)
	43327	Esophagogastric fundoplasty partial or complete; laparotomy
	43328	;thoracotomy
	43332	Repair, paraesophageal hiatal hernia (including fundoplication), via laparotomy, except neonatal; without implantation of mesh or other prosthesis
	43333	; with implantation of mesh or other prosthesis
	43334	Repair, paraesophageal hiatal hernia (including fundoplication), via

CODES	NUMBER	DESCRIPTION
		thoracotomy, except neonatal; without implantation of mesh or other prosthesis
	43335	; with implantation of mesh or other prosthesis
	43336	Repair, paraesophageal hiatal hernia (including fundoplication), via thoracoabdominal incision, except neonatal; without implantation of mesh or other prosthesis
	43337	; with implantation of mesh or other prosthesis
HCPCS	None	