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Medical Policy Manual

**Topic:** Gastroesophageal 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**

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.

**Background**

Gastroesophageal reflux disease (GERD) is a chronic medical condition, defined as “troublesome symptoms and/or complications” caused by reflux or regurgitation of stomach acid.[1] 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%. [2] 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.[1] 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 Fundoplication with Paraesophageal Hiatal Hernia Repair**

The hiatus is an opening in the diaphragm where the distal esophagus passes through to enter the abdomen. A hiatal hernia occurs when the stomach bulges up into the thorax (chest) through the hiatus. Hiatal hernias are classified according to their severity and location:

- **Type I** - Protrusion of the upper part of the stomach and esophagus (gastroesophageal junction) into chest is a sliding hiatal hernia and is the most common type (over 95% of hiatal hernias are of the sliding type).
- **Type II** - A paraesophageal hiatal hernia occurs when the esophagus and gastroesophageal junction to the stomach remains in their normal location but part of the stomach protrudes through the hiatus next to the esophagus.
- **Type III** – Combination of both type I and II hiatal hernias when the stomach and esophagus protrude into the chest and the fundus of the stomach lies above the gastroesophageal junction. A "giant" hiatal hernia is a subset of type III hiatal hernias and defined when greater than 50% of the stomach has protruded into the chest.
- **Type IV** – Defined as the presence of a structure other than the stomach that protrudes into the chest (e.g. colon, small bowel).

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 or III hiatal hernias, occur when the stomach, and in some cases the gastroesophageal junction (GEJ), herniates through the diaphragmatic esophageal hiatus into the mediastinum. 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 are common as they account for most of the complications associated with hiatal hernias, including but not limited to obstruction, perforation and strangulation.

**Esophagogastric Fundoplication in Patients with Pulmonary Fibrosis**

Idiopathic pulmonary fibrosis (IPF) is a progressive lung disease which is often associated with additional comorbidities (e.g., 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. It is hypothesized that fundoplication surgery may offer increased benefit over medication treatment by reducing acid as well as microaspirations of the gastric contents into the lungs.

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 transeosophageal endoscopic therapies for GERD, which are addressed separately in Surgery Policy No. 110 (see Cross References).

**MEDICAL POLICY CRITERIA**

**Notes:** This policy addresses adults only. For the purposes of this policy, adult is defined as age 18 years or older. This policy does not address fundoplication in children and adolescents, which may be considered medically necessary.

**I.** Initial esophagogastric fundoplication may be considered **medically necessary** for the treatment of symptomatic gastroesophageal reflux disease (e.g., heartburn, regurgitation) when all of the following criteria I.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

B. **Medication therapy** that meets at least one of the following:

1. A 6-month total trial of proton pump inhibitors (PPIs), including at least two different PPIs, is ineffective, contraindicated, or not tolerated. A minimum 2 month trial is required for each PPI trial; 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.

C. There is objective diagnostic confirmation 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.** Repeat esophagogastric fundoplication for a failed previous antireflux procedure may be considered **medically necessary** when either of the following criteria (II.A or II.B) are met:

A. **Criteria I. A-C** for esophagogastric fundoplication above are met; or
B. Repeat surgery is for a documented mechanical failure of previous antireflux procedure (e.g., obstruction).

III. Initial or repeat esophagogastric fundoplication may be considered **medically necessary** for any of the following:

A. In patients with pulmonary fibrosis with symptomatic or asymptomatic gastroesophageal reflux disease; or

B. When the procedure is performed with a paraesophageal hiatal hernia, and documentation of a paraesophageal type of hiatal hernia (type II, III, or IV) is confirmed by imaging. (Types are listed in policy Description section.) A paraesophageal hernia must be documented for coverage of paraesophageal hernia repair; or

C. When the procedure is performed with esophageal myotomy in patients with achalasia.

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

V. The following surgical procedures are considered **investigational** for the treatment of gastroesophageal reflux:

A. Distal or partial gastrectomy performed with or without any of the following:
   
   1. Gastroduodenostomy
   2. Gastrojejunostomy
   3. Roux-en-Y reconstruction

B. Hiatal hernia repair without fundoplication, including repair of sliding or paraesophageal hernia.

**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.

**Fundoplication**

**Systematic Reviews**
In 2010, The Cochrane Collaboration published a systematic review on medical versus surgical management for GERD in adults.\[9\] 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.\[10-13\] 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. Overall, the authors concluded that in the short- to medium-term there is evidence that laparoscopic fundoplication is more effective than medical management.

A 2015 update concluded that there is considerable uncertainty in the balance of benefits versus harms of laparoscopic fundoplication compared to long-term medical treatment with proton pump inhibitors.\[14\] Four randomized controlled trials were included for meta-analysis, consisting of three studies previously reported in the 2010 review, and longer term follow-up for the Anvari study.\[15\] The available evidence was rated low or very low, and further high-quality studies are needed.

Randomized Controlled Trials

Included in the publication of the 2015 Cochrane review, Anvari and colleagues reported 3-year outcomes from a prospective RCT (one-year results were included in the 2010 Cochrane review).\[15\] Of note, \textit{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

Surgical Treatment of GERD Patients with Pulmonary Fibrosis

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Current evidence regarding fundoplication in patients with pulmonary fibrosis (PF) mainly consist of case series\cite{16-18} and review articles, which indicated that silent reflux, or asymptomatic GERD, occurs in about one third of PF patients.\cite{6,8} Only a single case series was identified regarding the efficacy of reflux surgery in patients with idiopathic PF (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.\cite{7} 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.

Gastrectomy

Gastrectomy involves a partial or full surgical removal of the stomach and is most often performed to treat cancer, non-cancerous tumors, perforation, polyps, ulcers, or obesity. In order to determine whether the benefits of surgical gastrectomy in patients with chronic GERD outweigh the risks, well-designed RCTs are necessary, comparing gastrectomy to medical therapy and accepted surgical interventions (fundoplication).

Nonrandomized Studies

Current evidence regarding the use of distal, partial or complete gastrectomy with or without gastroduodenostomy, gastrojejunostomy, or Roux-en-Y reconstruction as a treatment of gastric reflux disease consists of small case series.\cite{19-21} These studies do not permit conclusions due to the small sample size, lack of a control group, differences in patient characteristics and surgical techniques, and other methodological limitations. In addition, several studies\cite{21-25} were identified which reported on GERD reduction after sleeve gastrectomy in obese patients; however, the primary focus of these studies was on weight reduction and the reduction of GERD symptoms was a secondary outcome. In order to isolate the direct effects of gastrectomy upon chronic GERD symptoms, well-designed RCTs are required which compare health outcomes of patients treated with gastrectomy versus medication or fundoplication.

Hiatal Hernia Repair without Fundoplication
Several studies were identified which reported an improvement in GERD symptoms associated with sliding type hernia repair; however, no studies were identified which evaluated the use of hiatal hernia repair as an independent treatment of gastric reflux disease.

Clinical Practice Guidelines

Three evidence-based clinical practice guidelines address surgical treatment of GERD. These guidelines offer differing recommendations concerning indications for surgery. No evidence-based clinical practice guidelines were identified which recommend fundoplication surgery as a treatment of GERD in patients with pulmonary fibrosis. In addition, no evidence-based clinical practice guidelines were identified which address the use of gastrectomy or hiatal hernia repair as a treatment of GERD.

Society of American Gastrointestinal and Endoscopic Surgeons

The Society of American Gastrointestinal and Endoscopic Surgeons (SAGES) guidelines recommend surgical therapy when the diagnosis of reflux is objectively confirmed, in individuals who:[26]

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)

In 2008, the American Gastroenterological Association (AGA) published a guideline regarding the management of gastroesophageal reflux disease which made the following recommendations:[1]

- “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**):
  o “for patients with an esophageal syndrome with or without tissue damage who are symptomatically well controlled on medical therapy.”
  o “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”

American College of Gastroenterology

In 2013, the American College of Gastroenterology (ACG)[27] issued a guideline for the diagnosis and management of gastroesophageal reflux disease and made numerous recommendations regarding the management and surgical options for GERD. The following are some of the major recommendations regarding PPI use and fundoplication:

• In patients with partial response to PPI therapy, increasing the dose to twice daily therapy or switching to a different PPI may provide additional symptom relief. (Conditional recommendation, low level evidence)

• Surgical therapy is a treatment option for long-term therapy in GERD patients. (Strong recommendation, high level of evidence)

• Surgical therapy is generally not recommended in patients who do not respond to PPI therapy. (Strong recommendation, high level of evidence)

• Surgical therapy is as effective as medical therapy for carefully selected patients with chronic GERD when performed by an experienced surgeon. (Strong recommendation, high level of evidence)

**Definitions**

• The strength of a recommendation was graded as "strong" when the desirable effects of an intervention clearly outweigh the undesirable effects and as "conditional" when there is uncertainty about the trade-offs.
• The level of evidence could range from "high" (implying that further research was unlikely to change the authors' confidence in the estimate of the effect) to "moderate" (further research would be likely to have an impact on the confidence in the estimate of effect) or "low" (further research would be expected to have an important impact on the confidence in the estimate of the effect and would be likely to change the estimate).

Summary

Esophagogastric Fundoplication

There is enough research to show that initial or repeat esophagogastric fundoplication improves symptomatic gastroesophageal reflux disease (GERD) for most patients with chronic GERD who have tried lifestyle changes and long-term use of proton pump inhibitors (PPIs), or in those with a documented mechanical failure from a previous antireflux procedure. It appears that initial or repeat esophagogastric fundoplication may also improve symptoms in patients with pulmonary fibrosis. When esophagogastric fundoplication is performed with a paraesophageal hiatal hernia repair, patients with a paraesophageal type of hiatal hernia may also benefit. Patients with achalasia may also have improved health outcomes when esophagogastric fundoplication is performed with an esophageal myotomy. Clinical guidelines based on research recommend fundoplication for select patients. Therefore, initial or repeat esophagogastric fundoplication may be considered medically necessary when policy criteria are met. Initial or repeat esophagogastric fundoplication for GERD is not medically necessary when policy criteria are not met.

Gastrectomy

There is not enough research to show that distal, partial or complete gastrectomy with or without gastroduodenostomy, gastrojejunostomy, or Roux-en-Y reconstruction improves health outcomes for people with gastrointestinal reflux disease (GERD). No clinical practice guidelines based on research recommend gastrectomy for people with GERD. Therefore, distal, partial or complete gastrectomy with or without gastroduodenostomy, gastrojejunostomy, or Roux-en-Y reconstruction is considered investigational as a treatment of GERD.

Hiatal Hernia Repair without Fundoplication

There is not enough research to show that hiatal hernia repair without fundoplication, including repair of sliding or paraesophageal hernia, improves health outcomes for people with gastrointestinal reflux disease (GERD). No clinical practice guidelines based on research recommend independent hiatal hernia repair as a treatment for GERD. Therefore hiatal hernia repair without fundoplication is considered investigational as an independent treatment of GERD.

REFERENCES


**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

*Peroral Endoscopic Myotomy for Treatment of Esophageal Achalasia*, Surgery, Policy No. 196

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