Regence

Medical Policy Manual Surgery, Policy No. 186

Gastroesophageal Reflux Surgery

Effective: April 1, 2025

Next Review: December 2025
Last Review: February 2025

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.

MEDICAL POLICY CRITERIA

I. Esophagogastric fundoplication may be considered **medically necessary** for one or more of the following:

   A. In children and adolescents age 17 years and younger; or

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

   C. When the procedure is performed with a paraesophageal hiatal hernia (Types II-IV as defined in List of Information Needed for Review), and the paraesophageal hiatal hernia is confirmed by imaging or endoscopy; or

   D. When the procedure is performed with esophageal myotomy in patients with achalasia; or

E. Initial esophagogastric fundoplication to treat symptomatic gastroesophageal reflux disease (e.g., heartburn, regurgitation) when all of the following criteria (1.-4.) are met:

1. A paraesophageal hiatal hernia repair (Types II-IV as defined in List of Information Needed for Review) is not requested or documented.
2. Symptoms are unresponsive to lifestyle modifications as appropriate to the individual patient (e.g., weight loss for overweight or obese patients, avoidance of late meals, elevation of the head of the bed); and
3. Medication therapy that meets one or more of the following:
    i. A 4-month total trial of proton pump inhibitors (PPIs) is ineffective, contraindicated, or not tolerated; or
    ii. PPIs are used for 12 or more consecutive months within the past 18 months, and surgery is considered an alternative to long-term medication use.
4. There is objective diagnostic confirmation by either of the following:
    i. Reflux and/or esophagitis is confirmed via endoscopy; or
    ii. If endoscopy is normal, objective evidence of reflux should include one or more of the following:
        a.) 24-hour ambulatory esophageal pH monitoring; or
        b.) Barium swallow.

F. Repeat esophagogastric fundoplication for a failed previous antireflux procedure when one or more of the following criteria are met:

1. Criteria I.E.1.-4. for initial esophagogastric fundoplication above are met; or
2. Repeat surgery is for a documented mechanical failure of previous antireflux procedure (e.g., obstruction).

II. Esophagogastric fundoplication is considered **not medically necessary** for the treatment of symptomatic gastroesophageal reflux disease (e.g., heartburn, regurgitation) when Criterion I. is not met.

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

A. Distal or partial gastrectomy performed with or without gastroduodenostomy, gastrojejunostomy, or Roux-en-Y reconstruction.

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

C. Hiatal hernia repair without fundoplication of greater than 180 degree wrap (e.g., Nissen, Toupet) due to prior bariatric surgery, including repair of sliding or paraesophageal hernia.

NOTE: A summary of the supporting rationale for the policy criteria is at the end of the policy.

LIST OF INFORMATION NEEDED FOR REVIEW

REQUIRED DOCUMENTATION:

It is critical that the list of information below is submitted for review to determine if the policy criteria are met. If any of these items are not submitted, it could our impact review and decision outcome.

- The specific surgical procedure and treatment plan;
- Medical records must document the following:
    - symptomatic gastroesophageal reflux disease (GERD; e.g., heartburn, regurgitation, etc);
    - any lifestyle modifications attempted and the outcomes (e.g., weight loss if appropriate, avoidance of late meals or foods that cause heartburn, avoidance of activities that cause heartburn, elevation of the head, etc.);
    - medication therapies, including PPIs, that have been attempted, and their outcomes;
    - diagnostic confirmation of reflux and/or esophagitis via endoscopy, 24-hour ambulatory esophageal pH monitoring, or barium swallow.
    - A paraesophageal hernia (**Types II-IV)** must be clearly documented by imaging or endoscopy for coverage of paraesophageal hernia repair. For example, esophagram, upper GI study, endoscopy, and CT scan are acceptable forms of documentation.
        - Hernia Classifications-

            - Type I – A hiatal hernia, commonly known as a sliding hernia, (type I), occurs when there is protrusion of the upper part of the stomach and esophagus (gastroesophageal junction) into the chest. This is the most common type (about 95%) of all hiatal hernias. This is also called a sliding hiatal hernia. A hiatal hernia of this type may also contain the upper segment of a sleeve gastrectomy or the pouch of a gastric band or gastric bypass. Additionally, if less than 50% of the stomach is located above the diaphragm, this is still considered a type I hiatal hernia and is not considered a paraesophageal hiatal hernia.
            - Type II - A paraesophageal hernia (type II) occurs when the esophagus and the gastroesophageal junction remain in their normal location but a part of the stomach, typically the fundus, protrudes through the hiatus next to the esophagus into the chest. These ‘pure' type II paraesophageal hiatal hernias seldom occur.
            - Type III – A paraesophageal hiatal hernia (type III) occurs when there is a 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 and rotates along its long axis in a rolling or twisting fashion, referred to as an organo-axial torsion. 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. The majority of paraesophageal hernias are type III. However,

all types of paraesophageal hiatal hernias make up about 5% of hiatal hernias but account for most of the hiatal hernia complications. The complications are primarily due to interference with the blood flow from the left gastric artery to the twisted fundus.
- Type IV – A paraesophageal hiatal hernia (type IV) occurs when a structure other than the stomach, such as the large intestine, small intestine, or omentum protrude through the hiatus into the chest.

▪ Repair of the typical Type I hiatal hernia (e.g. sliding hernias) cannot be coded by a paraesophageal hernia (Types II-IV) repair code per CPT code definitions. The paraesophageal hiatal hernia repair codes cannot be reported unless a paraesophageal hiatal hernia is clearly documented.

- Indicate if request is for an initial treatment or a repeat esophagogastric fundoplication and reason for the need to repeat the procedure (e.g., continued symptoms, mechanical failure, etc.)
- Presence of other conditions, such as pulmonary fibrosis, hiatal hernia, achalasia, etc.

CROSS REFERENCES

1. Bariatric Surgery, Surgery, Policy No. 58
2. Transesophageal Endoscopic Therapies for Gastroesophageal Reflux Disease (GERD), Surgery, Policy No. 110
3. Magnetic Esophageal Ring to Treat Gastroesophageal Reflux Disease (GERD), Surgery, Policy No. 190
4. Peroral Endoscopic Myotomy for Treatment of Esophageal Achalasia, Surgery, Policy No. 196
5. Hiatal Hernia Repair / Gastropexy When Performed With Major Surgical Procedures, Reimbursement Policy, Surgery, Policy No. 104

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

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 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 usually required as they account for most of the complications associated with hiatal hernias, including but not limited to obstruction, perforation and strangulation.[3] In some cases, patients may exhibit a paraesophageal hiatal hernia with additional symptoms of GERD, requiring not only a hiatal hernia repair, but additionally a fundoplication.[4]

Hiatal hernia classification

The hiatus is an opening in the diaphragm where the distal esophagus passes through to enter the abdomen. A hiatal hernia occurs when intrabdominal contents, such as the stomach, bulge up into the chest through the hiatus. There are four types of hiatal hernias:[5]

- Type I – A hiatal hernia, commonly known as a sliding hernia, (type I), occurs when there is protrusion of the upper part of the stomach and esophagus (gastroesophageal junction) into the chest. This is the most common type (about 95%) of all hiatal hernias. This is also called a sliding hiatal hernia. A hiatal hernia of this type may also contain the upper segment of a sleeve gastrectomy or the pouch of a gastric band or gastric bypass. Additionally, if less than 50% of the stomach is located above the diaphragm, this is still considered a type I hiatal hernia and is not considered a paraesophageal hiatal hernia.

- Type II - A paraesophageal hernia (type II) occurs when the esophagus and the gastroesophageal junction remain in their normal location but a part of the stomach, typically the fundus, protrudes through the hiatus next to the esophagus into the chest. These ‘pure' type II paraesophageal hiatal hernias seldom occur.

- Type III – A paraesophageal hiatal hernia (type III) occurs when there is a 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 and rotates along its long axis in a rolling or twisting fashion, referred to as an organo-axial torsion. 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. The majority of paraesophageal hernias are type III. However, all types of paraesophageal hiatal hernias make up about 5% of hiatal hernias but account for most of the hiatal hernia complications. The complications are primarily due to interference with the blood flow from the left gastric artery to the twisted fundus.

- Type IV – A paraesophageal hiatal hernia (type IV) occurs when a structure other than the stomach, such as the large intestine, small intestine, or omentum protrude through the hiatus into the chest.

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 (e.g., 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.[6-9] 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.[6]

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).

EVIDENCE SUMMARY

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

A systematic review published by Li (2023) compared laparascopic Nissen and Toupet fundoplications in patients with GERD from eight clinical trials.[10] Primary outcomes included postoperative reflux recurrence, postoperative heartburn, dysphagia and postoperative chest pain, patient satisfaction, and several other clinically important measures. The results of the review showed no significant difference between the Nissen and Toupet surgery types for the majority of outcomes. Those receiving the Toupet procedure had lower lower esophageal sphincter pressure, fewer postoperative dysphagia and inability to belch in the short and long term as well as less gas bloating in the short term when compared to the Nissen procedures. Both procedure types were shown to be effective in treating GERD.

In 2018, Richter reported results from a systematic review with network meta-analysis or randomized controlled trials comparing efficacy of laparoscopic Nissen fundoplication (LNF) to proton pump inhibitors in patients with GERD.[11] The authors also compared the Nissen procedure to transoral incisionless fundoplication, which is not within the scope of this policy, but is summarized elsewhere (see Cross References). Overall, 7 trials were included, totalling 1128 patients. Network meta-analysis using Bayesian methods under random-effects multiple treatment comparisons were implemented for analysis, as well as ranking probability by surface under the cumulative ranking curve. Patients who underwent LNF had a higher probability of persistent esophagitis (0.38) than those on PPI therapy (0.19). Out of all the

interventions studied, LNF had the highest probability of increasing percent time at pH <4 (0.99), followed by PPIs (0.64), and LNF also had a higher probability of increasing patients' health-related quality of life (0.66) than those on PPI therapy (0.05).

In 2010, The Cochrane Collaboration published a systematic review on medical versus surgical management for GERD in adults.[12] 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.[13-16] 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.[17] 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.[18] The available evidence was rated low or very low, and further high-quality studies are needed.

Randomized Controlled Trials

In 2017, Emken reported results of a secondary analysis of an industry sponsored multicenter randomized controlled trial comparing anti-reflux surgery (open fundoplication) to proton pump inhibitor (omeprazole) therapy.[19] From the same study, 3-year trial results were described by Lundell in 2000,[20] followed by 12-year outcomes in 2009[21]. Several of the authors were former employees of the industry sponsor.

> Study design: Three hundred and ten patients across 16 centers in 4 Nordic countries were originally enrolled in the trial, randomized in a 1:1 design (N=155 in each arm). Overall study duration was 14 years, from 1991-2005. In a pre-entry study period, all patients were treated with omeprazole 20mg twice daily with the option of increasing to 40mg if needed to achieve healing of esophageal lesions and control of symptoms. Of the 155 patients randomized to open fundoplication, 144 went on to have surgery; 129 had data available at 3-years follow-up. Of the 154 patients in the omeprazole therapy group (one dropped out prior to starting therapy), 139 had 3-year data available. The secondary analysis report (2017) included 1- and 10-year outcomes from patients who underwent surgery (N=137) and long-term treatment with omeprazole 20–60mg daily (N=108).
>
> Outcomes from 1-, 3-, 10-, and 12-years are summarized here:
>
> - At 3-years follow-up, the authors concluded efficacy from both approaches when omeprazole dose was adjusted over time.
> - In 2009, 12-year results were available for 71 who were given omeprazole (46%) and 53 treated with surgery (37%).
>   - There was no difference in percent of patients in continuous remission between treatment groups (including those who had a dose adjustment and those who did not).

    - Of the patients who underwent surgery, 38% required a change in therapeutic strategy (e.g., to medical therapy or additional surgeries), compared to 15% of those on omeprazole.
    - Adverse events: Therapies were generally well-tolerated in both groups, though heartburn and regurgitation were significantly more common in patients given omeprazole; whereas dysphagia, rectal flatulence, and the inability to belch or vomit were significantly more common in surgical patients. Over the entire follow-up period, fatal outcomes and those of heart-related cause were more common in the omeprazole group than the surgery group. Mean hemoglobin values did not change over time in either group, though mean ferritin levels increased after ten years in the medication treated group. Procedural complications were listed as more common serious adverse events in the surgery group as compared to the omeprazole group, as expected. Authors reported no surgery-related deaths in the original study; two of the surgery patients died of heart-related causes, and two experienced non-fatal heart attacks. In the omeprazole treated group, 8 patients died of heart-related causes, and 9 experienced non-fatal heart attacks. The authors reported that an Food and Drug Administration analysis of these events concluded that baseline differences between groups may have biased the safety outcomes. For example, the median age was four years greater in the medication group, and more patients had experienced a previous heart attack in the medication group as compared to the surgery group (six and zero, respectively).
- At 1- and 10-years follow-up, data were available for 108 patients in the omeprazole group, and 137 patients in the surgery group. One hundred fourteen patients had complete data for both timepoints, and 79 had only 1-year data. There were no statistically significant differences in demographics, manometry measurements, or 24-hour pH-monitoring measurements between those with complete data versus those with only 1-year of data.
    - In those who underwent surgery, measurement of lower esophageal sphincter (LOS) function (via manometry) showed statistically significant increase in median resting pressure at 1-year, which was sustained at 10-years. There were no significant changes in resting pressure in the omeprazole group.
    - Those in the surgery group had statistically significant increases in median total and intra-abdominal length of LOS at 1- and 10-years. In the omeprazole group, the median total and intra-abdominal length of LOS did not change from baseline to the 1-year manometry, however, at 10-years the results were comparable to the surgery group.

Included in the publication of the 2015 Cochrane review, Anvari reported 3-year outcomes from a prospective RCT (one-year results were included in the 2010 Cochrane review).[18] 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

SURGICAL TREATMENT OF GERD PATIENTS WITH PULMONARY FIBROSIS

Current evidence regarding fundoplication in patients with pulmonary fibrosis (PF) mainly consist of case series[22-24] and review articles, which indicated that silent reflux, or asymptomatic GERD, occurs in about one third of PF patients.[7, 9] 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.[8] 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).

Systematic Reviews and Randomized Controlled Trials

In 2016, Oor published results of a systematic review and meta-analysis of 33 studies examining the impact of laparoscopic sleeve gastrectomy on prevalence of GERD.[25] Pooled data from seven studies using validated symptom questionnaires for new-onset of GERD symptoms resulted in a 20% incidence following LSG (follow-up time ranging from one- to 60-months). There was heterogeneity amongst these studies (I^2=68%). For difference in prevalence of GERD before and after LSG, as reported by questionnaire, the pooled risk difference was found to be 4.3%; with heterogeneity present (I^2=89%). Of the 24 studies reviewed, the authors found new-onset GERD symptom incidence to range from zero to 34.9%. Data for new-onset esophagitis, changes in the use of antireflux medication, 24-hour pH monitoring, manometry, and combined pH-impedance results could not be pooled. The authors therefore concluded that LSG could induce serious GERD symptoms in patients with no preoperative GERD complaints. The heterogeneity found in analyses may be due to a lack of a standardized approach to LSG, as well has the variability in follow-up length. The authors also noted that range in prevalence of GERD symptoms may be in part due to the variability in reported preoperative BMI, as the LSG will be a more technically challenging procedure in those with a BMI of 60 kg/m^2 versus those with a BMI of 40 kg/m^2.

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.[26-28] 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[28-32] 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.

PRACTICE GUIDELINE SUMMARY

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:[33]

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

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**):
    - "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"

AMERICAN COLLEGE OF GASTROENTEROLOGY

In 2013, the American College of Gastroenterology (ACG) issued a guideline for the diagnosis and management of gastroesophageal reflux disease and made numerous recommendations regarding the management and surgical options for GERD.[34] 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.

There is not enough research to show that initial or repeat esophagogastric fundoplication for GERD improves health outcomes when policy criteria are not met. Therefore, initial or repeat esophagogastric fundoplication for GERD when policy criteria are not met is considered not medically necessary.

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.

There is not enough research to show that hiatal hernia repair without fundoplication of greater than 180 degree wrap (e.g., Nissen, Toupet) due to prior bariatric surgery, 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 hiatal hernia repair without fundoplication of greater than 180 degree wrap (e.g., Nissen, Toupet) due to prior bariatric surgery, including repair of sliding or paraesophageal hernia as a treatment for GERD. Therefore, hiatal hernia repair without fundoplication of greater than 180 degree wrap (e.g., Nissen, Toupet) due to prior bariatric surgery, including

repair of sliding or paraesophageal hernia is considered investigational as a treatment of GERD.

REFERENCES

1. Kahrilas PJ, Shaheen NJ, Vaezi MF, et al. American Gastroenterological Association Medical Position Statement on the management of gastroesophageal reflux disease. *Gastroenterology.* 2008;135(4):1383-91, 91 e1-5. PMID: 18789939
2. Dent J, El-Serag HB, Wallander MA, et al. Epidemiology of gastro-oesophageal reflux disease: a systematic review. *Gut.* 2005;54(5):710-7. PMID: 15831922
3. Mori T, Nagao G, Sugiyama M. Paraesophageal hernia repair. *Ann Thorac Cardiovasc Surg.* 2012;18:297-305. PMID: 22850094
4. Muller-Stich BP, Achtstatter V, Diener MK, et al. Repair of Paraesophageal Hiatal Hernias-Is a Fundoplication Needed? A Randomized Controlled Pilot Trial. *Journal of the American College of Surgeons.* 2015;221(2):602-10. PMID: 25868406
5. Kohn GP, Price RR, DeMeester SR, et al. Guidelines for the management of hiatal hernia. *Surgical endoscopy.* 2013;27(12):4409-28. PMID: 24018762
6. Lee JS, Ryu JH, Elicker BM, et al. Gastroesophageal reflux therapy is associated with longer survival in patients with idiopathic pulmonary fibrosis. *American journal of respiratory and critical care medicine.* 2011;184(12):1390-4. PMID: 21700909
7. Morehead RS. Gastro-oesophageal reflux disease and non-asthma lung disease. *Eur Respir Rev.* 2009;18:233-43. PMID: 20956148
8. Linden PA, Gilbert RJ, Yeap BY, et al. Laparoscopic fundoplication in patients with end-stage lung disease awaiting transplantation. *J Thorac Cardiovasc Surg.* 2006;131:438-46. PMID: 16434276
9. Pashinsky YY, Jaffin BW, Litle VR. Gastroesophageal reflux disease and idiopathic pulmonary fibrosis. *The Mount Sinai journal of medicine, New York.* 2009;76(1):24-9. PMID: 19170215
10. Li G, Jiang N, Chendaer N, et al. Laparoscopic Nissen Versus Toupet Fundoplication for Short- and Long-Term Treatment of Gastroesophageal Reflux Disease: A Meta-Analysis and Systematic Review. *Surgical innovation.* 2023;30(6):745-57. PMID: 36998190
11. Richter JE, Kumar A, Lipka S, et al. Efficacy of Laparoscopic Nissen Fundoplication vs Transoral Incisionless Fundoplication or Proton Pump Inhibitors in Patients With Gastroesophageal Reflux Disease: A Systematic Review and Network Meta-analysis. *Gastroenterology.* 2018. PMID: 29305934
12. Wileman SM, McCann S, Grant AM, et al. Medical versus surgical management for gastro-oesophageal reflux disease (GORD) in adults. *Cochrane Database Syst Rev.* 2010(3):CD003243. PMID: 20238321
13. Anvari M, Allen C, Marshall J, et al. A randomized controlled trial of laparoscopic nissen fundoplication versus proton pump inhibitors for treatment of patients with chronic gastroesophageal reflux disease: One-year follow-up. *Surgical innovation.* 2006;13(4):238-49. PMID: 17227922
14. Lundell L, Attwood S, Ell C, et al. Comparing laparoscopic antireflux surgery with esomeprazole in the management of patients with chronic gastro-oesophageal reflux disease: a 3-year interim analysis of the LOTUS trial. *Gut.* 2008;57(9):1207-13. PMID: 18469091

15. Mahon D, Rhodes M, Decadt B, et al. Randomized clinical trial of laparoscopic Nissen fundoplication compared with proton-pump inhibitors for treatment of chronic gastro-oesophageal reflux. *The British journal of surgery.* 2005;92(6):695-9. PMID: 15898130
16. Grant A, Wileman S, Ramsay C, et al. The effectiveness and cost-effectiveness of minimal access surgery amongst people with gastro-oesophageal reflux disease - a UK collaborative study. The REFLUX trial. *Health Technol Assess.* 2008;12(31):1-181, iii-iv. PMID: 18796263
17. Garg Sushil K, Gurusamy Kurinchi S. Laparoscopic fundoplication surgery versus medical management for gastro-oesophageal reflux disease (GORD) in adults. Cochrane Database of Systematic Reviews: John Wiley & Sons, Ltd, 2015.
18. Anvari M, Allen C, Marshall J, et al. A randomized controlled trial of laparoscopic Nissen fundoplication versus proton pump inhibitors for the treatment of patients with chronic gastroesophageal reflux disease (GERD): 3-year outcomes. *Surgical endoscopy.* 2011;25(8):2547-54. PMID: 21512887
19. Emken BG, Lundell LR, Wallin L, et al. Effects of omeprazole or anti-reflux surgery on lower oesophageal sphincter characteristics and oesophageal acid exposure over 10 years. *Scandinavian journal of gastroenterology.* 2017;52(1):11-17. PMID: 27593706
20. Lundell L, Miettinen P, Myrvold HE, et al. Long-term management of gastro-oesophageal reflux disease with omeprazole or open antireflux surgery: results of a prospective, randomized clinical trial. The Nordic GORD Study Group. *European journal of gastroenterology & hepatology.* 2000;12(8):879-87. PMID: 10958215
21. Lundell L, Miettinen P, Myrvold HE, et al. Comparison of outcomes twelve years after antireflux surgery or omeprazole maintenance therapy for reflux esophagitis. *Clinical gastroenterology and hepatology : the official clinical practice journal of the American Gastroenterological Association.* 2009;7(12):1292-8; quiz 60. PMID: 19490952
22. Raghu G, Yang ST, Spada C, et al. Sole treatment of acid gastroesophageal reflux in idiopathic pulmonary fibrosis: a case series. *Chest.* 2006;129:794-800. PMID: 16537884
23. Patti MG, Tedesco P, Golden J, et al. Idiopathic pulmonary fibrosis: how often is it really idiopathic? *J Gastrointest Surg.* 2005;9:1053-6; discussion 56-8. PMID: 16269375
24. Allaix ME, Fisichella PM, Noth I, et al. Idiopathic pulmonary fibrosis and gastroesophageal reflux. Implications for treatment. *J Gastrointest Surg.* 2014;18(1):100-4; discussion 04-5. PMID: 24002768
25. Oor JE, Roks DJ, Unlu C, et al. Laparoscopic sleeve gastrectomy and gastroesophageal reflux disease: a systematic review and meta-analysis. *American journal of surgery.* 2016;211(1):250-67. PMID: 26341463
26. Galvez-Valdovinos R, Cruz-Vigo JL, Marin-Santillan E, et al. Cardiopexy with Ligamentum Teres in Patients with Hiatal Hernia and Previous Sleeve Gastrectomy: An Alternative Treatment for Gastroesophageal Reflux Disease. *Obesity surgery.* 2015;25(8):1539-43. PMID: 25990381
27. Lacy A, Ibarzabal A, Pando E, et al. Revisional surgery after sleeve gastrectomy. *Surg Laparosc Endosc Percutan Tech.* 2010;20:351-6. PMID: 20975509
28. Langer FB, Bohdjalian A, Shakeri-Leidenmuhler S, et al. Conversion from sleeve gastrectomy to Roux-en-Y gastric bypass--indications and outcome. *Obesity surgery.* 2010;20(7):835-40. PMID: 20393810
29. Afaneh C, Costa R, Pomp A, et al. A prospective randomized controlled trial assessing the efficacy of omentopexy during laparoscopic sleeve gastrectomy in reducing postoperative gastrointestinal symptoms. *Surgical endoscopy.* 2015;29(1):41-7. PMID: 24962864

30. Page MP, Kastenmeier A, Goldblatt M, et al. Medically refractory gastroesophageal reflux disease in the obese: what is the best surgical approach? *Surgical endoscopy.* 2014;28(5):1500-4. PMID: 24310740
31. Chiu S, Birch DW, Shi X, et al. Effect of sleeve gastrectomy on gastroesophageal reflux disease: a systematic review. *Surgery for obesity and related diseases : official journal of the American Society for Bariatric Surgery.* 2011;7:510-5. PMID: 21130052
32. Pallati PK, Shaligram A, Shostrom VK, et al. Improvement in gastroesophageal reflux disease symptoms after various bariatric procedures: review of the Bariatric Outcomes Longitudinal Database. *Surgery for obesity and related diseases : official journal of the American Society for Bariatric Surgery.* 2014;10(3):502-7. PMID: 24238733
33. Stefanidis D, Hope WW, Kohn GP, et al. Guidelines for surgical treatment of gastroesophageal reflux disease. *Surgical endoscopy.* 2010;24(11):2647-69. PMID: 20725747
34. Katz PO, Gerson LB, Vela MF. Guidelines for the diagnosis and management of gastroesophageal reflux disease. *Am J Gastroenterol.* 2013;108:308-28; quiz 29. PMID: 23419381

CODES

NOTES:

- Repair of the typical Type I hiatal hernia cannot be coded by a paraesophageal hernia repair code per CPT code definitions.
- The paraesophageal hiatal hernia repair codes (i.e., 43281) cannot be reported unless a paraesophageal hiatal hernia is clearly documented.
- CPT 43280 cannot be reported unless a fundoplication is performed.
- There are related procedures without specific CPT codes, including sliding (type I) hiatal hernia repair and the Hill procedure, and these are reported by unlisted codes.

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 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
	43338	Esophageal lengthening procedure (eg, Collis gastroplasty or wedge gastroplasty) (List separately in addition to code for primary procedure)

Codes	Number	Description
	43631	Gastrectomy, partial, distal; with gastroduodenostomy
	43632	;with gastrojejunostomy
	43633	;with roux-en-Y reconstruction
	43634	;with formation of intestinal pouch
HCPCS	None	

Date of Origin: *November 2012*