Cohere Medicare Advantage Policy - Laparoscopic Hiatal Hernia Repair and Anti-GERD Surgical Treatments

Clinical Guidelines for Medical Necessity Review

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Important Notices

Notices & Disclaimers:

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Other Notices:

Guideline Information:

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Type: [**X**] Adult (18+ yo) | [**X**] Pediatric (0-17 yo)

Table of Contents

Medical Necessity Criteria

Service: Laparoscopic Hiatal Hernia Repair and Anti-GERD Surgical Treatments

Benefit Category

Not applicable.

Please Note: This may not be an exhaustive list of all applicable Medicare benefit categories for this item or service.

Related CMS Documents

Please refer to the CMS Medicare Coverage Database for the most current applicable CMS National Coverage.[21,22,30,31]

- Local Coverage Determination (LCD) (L35080): Select Minimally Invasive GERD Procedures.
- Local Coverage Determination (LCD) (L34659): Endoscopic treatment of GERD.
- Billing and Coding A56395: Endoscopic treatment of GERD.
- Billing and Coding A56863: Select minimally invasive GERD procedures.

Recommended Clinical Approach

Hiatal hernia (HH) is a common structural defect of the diaphragm that occurs when the anterior stomach (fundus) protrudes through the opening where the esophagus passes from the thorax to the abdomen (diaphragmatic hiatus). HH may be asymptomatic or accompanied by gastroesophageal reflux disease (GERD) and is usually diagnosed through a barium swallow test or diagnostic imaging. HH are classified into 4 types. In type I (sliding hiatal hernia), the gastroesophageal junction (GEJ) moves headward through the hiatus into the thorax. In type II (paraesophageal hernia), the gastric fundus herniates through the hiatus into the thorax, but the GEJ remains in the abdomen. Type III is a combination of types I and II, where the GEJ and stomach herniate into the thorax. Type IV is a type III HH with herniation of other organs into the thorax, such as the colon and spleen.[1]

The 3 dominant pathogenic theories for HH include: (1) intra-abdominal pressure forces the GEJ into the thorax; (2) esophageal shortening displaces the GEJ into the thorax; and (3) GEJ migrates into the chest due to a widening of the diaphragmatic hiatus due to molecular and cellular changes.[2]

Treatment for HH is directed at symptoms of GERD, if present. Symptomatic HH (types II-IV) may require repair using a transabdominal or transthoracic approach. Initial or revision laparoscopic HH repair may also be medically necessary during bariatric surgery. A single laparoscopic HH repair is sufficient for most patients. Laparoscopic repair with suturing of the hiatal pillars followed by fundoplication is the standard medical practice for HH. Mesh reinforcement, commonly located at the posterior esophageal hiatus, is commonly used to lower recurrence rates.[3] Additionally, fundoplication is used to repair paraesophageal HH and reduce the risk of postoperative gastrointestinal reflux as well as reinforce the repair to prevent recurrence. Laparoscopic esophagogastric fundoplasty is a procedure that involves wrapping the upper part of the stomach around the lower part of the esophagus.[1] Physicians may choose this procedure for patients with gastroesophageal reflux. Laparoscopic HH surgery is generally not considered appropriate for patients with asymptomatic HH without objective evidence or a high risk of reflux or micro-aspiration.[4]

Evaluation of Clinical Harms and Benefits

Cohere Health uses the criteria below to ensure consistency in reviewing the conditions to be met for coverage of laparoscopic hiatal hernia repair and anti-GERD surgical treatments. This process helps to prevent both incorrect denials and inappropriate approvals of medically necessary services. Specifically, limiting incorrect approvals reduces the risks associated with unnecessary procedures, such as complications from surgery, infections, and prolonged recovery times.

The **potential clinical harms** of using these criteria may include:

- The surgical placement of mesh to prevent the recurrence of hiatal hernias has been associated with infection, erosion, seroma, and pain. The use of synthetic mesh has been associated with the development of esophageal erosion, stricture, dysphagia, obstruction, and esophageal stenosis.[5] Less common adverse effects of anchoring a mesh to the diaphragm include cardiac injuries that manifest as

cardiac tamponade, especially when a helical tacker is used in this region.[15]

- Robotic surgery in laparoscopic hiatal hernia repair and anti-GERD surgery using the DaVinci system is subject to substantial costs and can result in higher rates of esophageal perforation and respiratory failure compared to conventional laparoscopy. Moreover, improvements in operating time, intraoperative and postoperative complications, and the length of hospital stay between robotic-assisted surgery and conventional laparoscopic hiatal hernia repair are debatable.[5,13]
- Depending on the surgical technique, symptoms (including the hiatal hernia itself) may recur and necessitate further medical or invasive management.[16,17]
- Increased healthcare costs and complications from the inappropriate use of emergency services and additional treatments.

The **potential clinical benefits** of using these criteria include:

- Hiatal hernia and anti-GERD surgery can provide a long-term cure for persistent heartburn, acid reflux, chest pain, dysphagia, and other debilitating upper gastrointestinal signs and symptoms.[4,14]
- Hiatal hernia surgery can result in long-term acid suppression, which reduces the risk of progression to esophageal adenocarcinoma.[4,14]
- Hernia recurrence decreases after laparoscopic paraesophageal hernia repair and mesh reinforcement, with similar results with synthetic and biologic meshes.[5]
- Adequate symptom control leads to freedom from long-term PPI use, which confers potential risks to bone and kidney health, as well as an increased risk of pneumonia.[23]
- Enhanced overall patient satisfaction and healthcare experience.

This policy includes provisions for expedited reviews and flexibility in urgent cases to mitigate risks of delayed access. Evidence-based criteria are employed to prevent inappropriate denials, ensuring that patients receive medically necessary care. The criteria aim to balance the need for effective treatment with the minimization of potential harms, providing numerous clinical benefits in helping avoid unnecessary complications from inappropriate care.

In addition, the use of these criteria is likely to decrease inappropriate denials by creating a consistent set of review criteria, thereby supporting optimal patient outcomes and efficient healthcare utilization.

Medical Necessity Criteria

Indications

- ➔ **Anti-reflux surgical treatment for GERD or laparoscopic hiatal hernia repair** are considered appropriate if **ANY** of the following is true[21,22]:
  - ◆ **Anti-reflux surgery** (fundoplication [(e.g., Dor, Nissen, or Toupet procedures]), WITH or WITHOUT hiatal hernia repair (types 1-4), is considered appropriate with **ALL** of the following[16,17]:
    - **ANY** of the following:
      - Without hiatal hernia repair (fundoplication only) with **ANY** of the following:
        - ◆ Gastroesophageal reflux symptoms or GERD complications (e.g., reflux esophagitis) not fully responsive to medical treatment (e.g., unsuccessful treatment with proton pump inhibitors (PPIs), histamine receptor antagonists, or antacids, for at least 3 successive months under the direction of a healthcare professional)[6]; **OR**
        - ◆ Gastroesophageal reflux symptoms present when medical treatment is contraindicated (e.g., intolerant or allergic to PPIs and/or histamine receptor antagonists); **OR**
        - ◆ The patient has **ANY** of the following[4]:
          - Documented evidence of micro-aspiration; **OR**
          - High risk for complications of micro-aspiration (e.g., lung transplant recipient); **OR**
      - With hiatal hernia (fundoplication with hiatal hernia repair) with **ANY** of the following:
        - ◆ Gastroesophageal reflux symptoms or GERD complications (e.g., reflux esophagitis) not fully responsive to medical treatment (e.g., unsuccessful treatment with proton pump

inhibitors (PPIs), histamine receptor antagonists, or antacids, for at least 3 successive months under the direction of a healthcare professional)[6]; **OR**
        - Gastroesophageal reflux symptoms present when medical treatment is contraindicated (e.g., intolerant or allergic to PPIs and/or histamine receptor antagonists); **OR**
        - The patient has any hiatal hernia with **ANY** of the following[4]:
            - Documented evidence of micro-aspiration; **OR**
            - High risk for complications of micro-aspiration (e.g., lung transplant recipient); **AND**
    - **ALL** of the following objective criteria are met[18]:
        - High-resolution manometry or barium esophagram rules out achalasia; **AND**
        - **ANY** of the following that confirms GERD (abnormal esophageal acid exposure):
            - Upper endoscopy (e.g., in the form of reflux esophagitis, peptic stricture, or Barrett's esophagus); **OR**
            - Ambulatory esophageal pH-metry; **OR**
            - Ambulatory esophageal pH-impedance testing; **OR**
- **Laparoscopic hiatal hernia repair** with or without fundoplication (e.g., Dor, Nissen, or Toupet procedures) and/or mesh placement is considered appropriate if **ALL** of the following[1-12]:
    - Hiatal hernia is confirmed by **ANY** of the following[5]:
        - Cross-sectional imaging (CT or MRI); **OR**
        - Contrast radiography (barium esophagram or upper GI series); **OR**
        - Esophagogastroduodenoscopy (EGD); **OR**
        - Esophageal manometry; **OR**
        - Detection during preoperative workup for bariatric surgery[15]; **AND**

- Hiatal hernia is designated as type 2, 3, or 4 and is associated with **ANY** of the following symptoms:
    - Acute rotation of the stomach (gastric volvulus), including but not limited to upside-down stomach (UDS)[1]; **OR**
    - Gastric outlet obstruction caused by the hernia; **OR**
    - Suspected or documented gastric strangulation; **OR**
    - Dysphagia or post-prandial fullness resulting from hernia-related mass effect and extrinsic compression on the lower esophagus[15]; **OR**
    - Persistent anemia when other causes have been excluded; **OR**

◆ **Revision** of prior hiatal hernia repair or fundoplication is considered appropriate with **ALL** of the following[1-12]:

- Evidence of failure of prior operation, including but not limited to recurrent hernia or migration of fundoplasty; **AND**
- Recurrent symptoms (e.g., any of the symptoms described above for initial procedure) or recurrent GERD symptoms that are refractory despite adequate trial of medical therapy with PPI and/or histamine antagonist and/or antacids; **OR**

◆ **TIF (Transoral Incisionless Fundoplication)** is considered appropriate with **ALL** of the following[21,22]:

- Symptomatic chronic GERD (at least 6 months of symptoms); **AND**
- Symptoms must not be completely responsive to Proton Pump Inhibitors (PPIs) as indicated by **ANY** of the following:
    - **ALL** of the following:
        - ◆ GERD health-related quality of life (HRQL) scores of less than or equal to 12 while on PPIs; **AND**
        - ◆ GERD HRQL scores of greater than or equal to 20 when off PPIs for 14 days; **OR**
    - A difference of greater than or equal to 10 of GERD HRQL scores between off and on therapy; **AND**
- **ANY** of the following:
    - No hiatal hernia; **OR**

- Hiatal hernia less than or equal to 2 cm, including instances where the hernia has been reduced to 2 cm or less by a successful laparoscopic hernia reduction procedure prior to the TIF procedure.

Non-Indications

➔ **Anti-reflux surgical treatment for GERD or laparoscopic hiatal hernia repair** is not considered appropriate if **ANY** of the following is **TRUE:**

- **Laparoscopic hiatal hernia repair** with or without fundoplication (e.g., Dor, Nissen, or Toupet procedures) and/or mesh placement is not considered appropriate with **ANY** of the following[9,21,22]:
  - The patient has an asymptomatic hiatal hernia and no objective evidence of GERD or GERD complications; **OR**
  - The patient does not meet the criteria as outlined above; **OR**
  - The request is for open surgery for hiatal hernia repair; **OR**
- **Magnetic sphincter augmentation (LINX Reflux Management System)** is not considered appropriate with **ANY** of the following[21,22]:
  - This procedure is clinically unproven and not medically necessary. There is inconclusive evidence of its effectiveness; **OR**
- **TIF (Transoral Incisionless Fundoplication)** is not considered appropriate with **ANY** of the following[21,22]:
  - Repeat TIF - this is clinically unproven and not medically necessary; there is inconclusive evidence of its effectiveness; **OR**
  - Any patient with a hiatal hernia greater than 2 cm, except where the hernia has been reduced to 2 cm or less by a successful laparoscopic hernia reduction procedure prior to the TIF procedure; **OR**
  - BMI greater than 35; **OR**
  - Esophagitis LA grade higher than B; **OR**
  - Barrett's esophagus greater than 2 cm; **OR**
  - Presence of achalasia; **OR**
  - Presence of esophageal ulcer; **OR**
  - Patient has not been on an appropriate trial of proton pump inhibitors (PPIs).

Level of Care Criteria

Inpatient or Outpatient.

Procedure Codes (CPT/HCPCS)

CPT/HCPCS Code	Code Description
43280	Laparoscopy, surgical, esophagogastric fundoplasty (e.g., Nissen, Toupet procedures)
43281	Laparoscopy, surgical, repair of paraesophageal hernia, includes fundoplasty, when performed; without implantation of mesh
43282	Laparoscopy, surgical, repair of paraesophageal hernia, includes fundoplasty, when performed; with implantation of mesh
43284	Laparoscopy, surgical, esophageal sphincter augmentation procedure, placement of sphincter augmentation device (ie, magnetic band), including cruroplasty when performed

Disclaimer: G, S, I, and N Codes are non-covered per CMS guidelines due to their experimental or investigational nature.

Medical Evidence

Daly et al. (2024) conducted systematic reviews to evaluate (i) surgical treatment of asymptomatic hiatal hernia versus surveillance, (ii) the use of mesh versus not, (iii) performing a fundoplication versus no fundoplication; and (iv) Roux-en-Y gastric bypass (RYGB) versus repeat fundoplication for recurrent hiatal hernia, with the aim of providing guidance regarding surgical decision making in the treatment of hiatal hernia. The expert panel suggested that select asymptomatic patients may be offered surgical repair when objective evidence exists of reflux or micro-aspiration or when patients are at high-risk for complications of micro-aspiration even in the absence of objective findings, such as lung transplant patients. The panel also suggested that conversion to RYGB for the management of recurrent hiatal hernia may be appropriate in certain patients without obesity and with recurrent type II, III, or IV hiatal hernia. The evidence for the routine use of mesh in hiatal hernia repair was inconclusive and the panel did not make a recommendation in this regard.[4]

Bhatt et al. (2023) systematically reviewed the perioperative outcomes of robotic and laparoscopic paraesophageal hernia (PEH) repair. Robotic surgery for large PEHs may offer benefits over standard laparoscopic approaches in decreasing conversion rates and duration of hospital stay. Some studies found a decrease inthe need for esophageal lengthening procedures and fewer long-term recurrences. The perioperative complication rate is similar between the two techniques in most studies; however, one large study of nearly 170,000 patients in the early years of robotics adoption demonstrated a higher rate of esophageal perforation and respiratory failure in the robotic group (2.2% increase in absolute risk). Cost is another disadvantage of robotic repair when compared to laparoscopic repair. Limitations of this systematic review include the non-randomized and retrospective nature of the studies.[13]

Geerts et al. (2023) reviewed the anatomic location of hiatal hernia recurrences to assess the high rates of recurrence despite mesh reinforcement. A retrospective analysis of video clips from the procedure in 54 patients who underwent revision hiatal hernia surgery revealed that the left-anterior quadrant of the esophageal hiatus was involved in 43 patients

(80%), the right-anterior quadrant in 21 patients (39%), the left-posterior quadrant in 21 patients (39%), and the right-posterior quadrant in 10 patients (19%). Based on these findings, the authors hypothesized that both posterior and anterior hiatal reinforcement might lower the recurrence rate of hiatal hernia.[3]

Analatos et al. (2020) report the results of a randomized, double-blind clinical trial (NCT04436159) that compares clinical outcomes and postoperative mechanical complications of para-oesophageal hernia repair employing total (Nissen) versus posterior partial (Toupet) fundoplication in 70 patients who had undergone hernia reduction and crural repair. Ogilvie dysphagia scores were stable at the 3- and 6-month follow-up in the Nissen group but significantly improved in the Toupet group at 6 months. At 6 months, Dakkak dysphagia scores were significantly higher in the Nissen group than in the Toupet group. Although quality of life (QoL) scores improved throughout the follow-up, at 3 and 6 months postoperatively, the absolute median improvement in the mental component of the QoL questionnaire was significantly higher in the Toupet group. At 6 months, radiologically confirmed recurrence of hernias occurred in 46% of patients in the Nissen group and 47% of patients in the Toupet group. Based on these findings, the authors conclude Toupet fundoplication shows reduced obstructive complications and improved QoL compared with Nissen fundoplication following para-oesophageal hernia repair.[14]

Several new therapies exist for the treatment of GERD and/or hiatal hernia. The LINX system seeks to control reflux with the implantation of a ring of magnetic beads around the distal esophagus, thereby creating an artificial sphincter. Broadly known as magnetic sphincter augmentation, this novel procedure appears to be well-tolerated by many patients, but the long-term efficacy and safety profile is not yet known simply by virtue of its short time on the market. Because this novel therapy does not yet have long-term efficacy results nor a diverse range of randomized, controlled, double-blinded trials of statistical rigor, it is premature to presume clinical outcomes and benefits, as well as long-term safety. For the same reason, this procedure cannot be considered equivalent or superior to the existing standard of surgical care.[19,20]

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Clinical Guideline Revision History/Information

Original Date: December 19, 2024.		
Review History		
Version 2	3/6/2025	• Created indications for fundoplication without hiatal hernia, previously absent from policy. • Clarified hiatal hernia repair criteria to ensure non-approval of asymptomatic type 1 HH (not medically appropriate). • Provided non-indication for LINX, novel and not yet clinically proven or medically necessary. • Per CMS guidance, provided indication for TIF approval, as well as coverage limitation as appropriate. Language taken directly from CMS and therefore not more stringent. • Added references. • Added indications for revision, previously absent from policy. • Modified criteria to allow manometry of barium esophagram for r/o of achalasia.