**Medical Coverage Policy |** Peroral Endoscopic Myotomy for Treatment of Esophageal Achalasia and Gastroparesis

**EFFECTIVE DATE:** 03|01|2024
**POLICY LAST REVIEWED:** 12|03|2025

## OVERVIEW

Esophageal achalasia is characterized by reduced numbers of neurons in the esophageal myenteric plexuses and reduced peristaltic activity, making it difficult for patients to swallow food and possibly leading to complications such as regurgitation, coughing, choking, aspiration pneumonia, esophagitis, ulceration, and weight loss. Peroral endoscopic myotomy (POEM) is a novel endoscopic procedure that uses the oral cavity as a natural orifice entry point to perform myotomy of the lower esophageal sphincter. This procedure is intended to reduce the total number of incisions needed and thus the overall invasiveness of surgery. Gastric peroral endoscopic myotomy (G-POEM) is a similar procedure with the exception that it myotomizes the pylorus rather than LES. Gastric peroral endoscopic myotomy (G-POEM) is a similar procedure with the exception that it myotomizes the pylorus rather than LES.

## MEDICAL CRITERIA

Not applicable

## PRIOR AUTHORIZATION

Not applicable

## POLICY STATEMENT

**Medicare Advantage Plans**

Peroral endoscopic myotomy is considered not covered as a treatment for pediatric and adult esophageal achalasia as the evidence is insufficient to determine the effects of the technology on health outcomes.

Gastric peroral endoscopic myotomy is considered not covered as a treatment for gastroparesis as the evidence is insufficient to determine the effects of the technology on health outcomes.

**Commercial Products**

Peroral endoscopic myotomy is considered not medically necessary as a treatment for pediatric and adult esophageal achalasia as the evidence is insufficient to determine the effects of the technology on health outcomes.

Gastric peroral endoscopic myotomy is considered not medically necessary as a treatment for gastroparesis as the evidence is insufficient to determine the effects of the technology on health outcomes.

## COVERAGE

Benefits may vary between groups and contracts. Please refer to the appropriate Benefit Booklet, Evidence of Coverage or Subscriber Agreement for applicable not medically necessary/not covered benefits/coverage.

## BACKGROUND

**Esophageal Achalasia**

Esophageal achalasia is characterized by reduced numbers of neurons in the esophageal myenteric plexuses and reduced peristaltic activity, making it difficult for patients to swallow food and possibly leading to complications such as regurgitation, coughing, choking, aspiration pneumonia, esophagitis, ulceration, and weight loss. Achalasia is estimated to affect 18 out of every 100,000 individuals in the U.S., and the incidence of 10.5 per 100,000 person-years, with increased rates reported with more advanced age.

**Treatment**

Treatment options for achalasia have included pharmacotherapy (eg, injections with botulinum toxin), pneumatic dilation, and laparoscopic Heller myotomy. Although the latter two are considered the standard treatments because of higher success rates and relatively long-term efficacy compared with pharmacotherapy, both are associated with a perforation risk of about 1%. Heller myotomy is the most invasive of the procedures, requiring laparoscopy and surgical dissection of the esophagogastric junction. One-year response rates of 86% and major mucosal tear rates requiring the subsequent intervention of 0.6% have been reported.

Peroral endoscopic myotomy (POEM) is a novel endoscopic procedure developed in Japan. POEM is performed with the patient under general anesthesia. After tunneling an endoscope down the esophagus toward the esophageal-gastric junction, a surgeon performs the myotomy by cutting only the inner, circular lower esophageal sphincter muscles through a submucosal tunnel created in the proximal esophageal mucosa. POEM differs from laparoscopic surgery, which involves the complete division of both circular and longitudinal lower esophageal sphincter muscle layers. Cutting the dysfunctional muscle fibers that prevent the lower esophageal sphincter from opening allows food to enter the stomach more easily.
Note that the acronym POEM in this review refers to *peroral endoscopic myotomy*.

For adults who have achalasia who receive POEM, the evidence includes systematic reviews of observational studies, a randomized controlled trial, nonrandomized comparative studies, and case series. The relevant outcomes are symptoms, functional outcomes, health status measures, resource utilization, and treatment-related morbidity. The comparative studies have primarily reported similar outcomes for POEM and for Heller myotomy in symptom relief, as assessed by the Eckardt score. Some studies have shown a shorter length of stay and less postoperative pain with POEM. However, potential imbalances in patient characteristics in these nonrandomized studies might have biased the treatment comparisons. In the case series, treatment success at short follow-up periods was reported for a high proportion of patients treated with POEM. However, the incidence of adverse events was relatively high, with POEM-specific complications, including subcutaneous emphysema, pneumothorax, and thoracic effusion, reported across studies. Additionally, a substantial proportion of patients undergoing POEM developed gastroesophageal reflux disease and esophagitis and required treatment. Case series do not permit conclusions about the efficacy of POEM relative to established treatment, and long-term outcomes of the procedure are not well described in the literature. The evidence is insufficient to determine the effects of the technology on health outcomes.

For pediatric patients who have achalasia who receive POEM, the evidence includes several nonrandomized studies and a systematic review. The relevant outcomes are symptoms, functional outcomes, health status measures, resource utilization, and treatment-related morbidity. The studies reported treatment success for POEM based on decreases in Eckardt scores and lower esophageal sphincter pressure. No randomized clinical trials have been reported. The evidence is insufficient to determine the effects of the technology on health outcomes.

**Gastroparesis**
Gastroparesis is characterized by symptoms of nausea, vomiting, bloating, early satiety, and pain, which is caused by delayed gastric emptying without mechanical obstruction. The estimated U.S. prevalence of difficult to ascertain due to the weak correlation of symptoms with gastric emptying which results in a high rate of underdiagnosis. Using data from 1996 to 2006, the estimated incidence per 100,000 persons, adjusted for age, was 9.6 for men and 37.8 for women. A systematic review of the literature determined that the prevalence of confirmed gastroparesis, characterized by symptoms and delayed gastric emptying, varies widely in the general population, with estimates ranging from 14 to 268 cases per 100,000 adults. Furthermore, the incidence of this condition spans from 1.9 to 6.3 per 100,000 person-years.

**Treatment**
Treatment options for gastroparesis have included dietary modification (smaller meal sizes, avoidance of carbonated beverages, smoking or high doses of alcohol, and in some cases enteral nutrition via jejunostomy), optimization of hydration and glycemic control, pharmacotherapy (eg, antiemetics or Metoclopramide, or off-

label medications for symptom control such as domperidone, erythromycin, tegaserod or centrally acting antidepressants), gastric electrical stimulation, venting gastrostomy, feeding jejunostomy, intra-pyloric botulinum injection, partial gastrectomy, and pyloroplasty.6, Gastric peroral endoscopic myotomy (G-POEM), which endoscopically performs the equivalent of pyloroplasty, is being investigated for the treatment of gastroparesis. G-POEM myotomizes the pylorus rather than the circular LES but otherwise consists of the same techniques described above.

For adults who have gastroparesis who receive gastric POEM (G-POEM), the evidence includes 2 meta-analyses, 2 RCT, and several nonrandomized studies. Relevant outcomes are symptoms, functional outcomes, health status measures, resource utilization, and treatment-related morbidity. The studies generally reported treatment success for G-POEM based on a decrease in Gastroparesis Cardinal Symptom Index (GCSI) score and ranged from 61% at 1 year to 75% at 3 years in the meta-analyses. One RCT demonstrated a notably higher success rate and improvement in gastric retention for G-POEM compared to a sham control group, with the most significant benefit observed in patients with diabetic gastroparesis. Another RCT indicated a trend towards superior 3-month clinical outcomes for POEM over botulinum toxin injection, although the 1-year clinical success rate on intention-to-treat analysis was not significantly higher. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

**Regulatory Status**
Peroral endoscopic myotomy uses available laparoscopic instrumentation and, as a surgical procedure, is not subject to regulation by the U.S. Food and Drug Administration.

## CODING

**Medicare Advantage Plans and Commercial Products:**
The following code(s) are not covered for Medicare Advantage Plans and not medically necessary for Commercial Products:

**43497** Lower esophageal myotomy, transoral (ie, peroral endoscopic myotomy [POEM])

## RELATED POLICIES

None

## PUBLISHED

Provider Update, February 2025
Provider Update, January 2024
Provider Update, March 2022
Provider Update, April 2021

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