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MEDICAL POLICY – 2.01.91

Peroral Endoscopic Myotomy for Treatment of Esophageal Achalasia and Gastroparesis

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Replaces:	N/A

RELATED MEDICAL POLICIES:

2.01.38	Transesophageal Endoscopic Therapies for Gastroesophageal Reflux Disease
7.01.137	Magnetic Esophageal Sphincter Augmentation to Treat Gastroesophageal Reflux Disease
8.01.17	Hematopoietic Cell Transplantation for Plasma Cell Dyscrasias, Including Multiple Myeloma and POEMS Syndrome

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POLICY CRITERIA | CODING | RELATED INFORMATION
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Introduction

Esophageal achalasia is a rare problem with the esophagus (the swallowing tube). It affects the ability to pass food through the esophagus and into the stomach. The muscles of the esophagus don't move food down, and the ring of muscles at the end of the esophagus don't relax to easily allow food into the stomach. This makes swallowing very difficult. A new surgery, POEM (peroral endoscopic myotomy), is being tried. A viewing scope with a special cutting blade is passed through the mouth and into the esophagus. Part of the muscle layer of the lower part of the esophagus, the sphincter, and the upper part of the stomach is removed. POEM is investigational. More and larger studies are needed to compare POEM with standard surgery to treat esophageal achalasia.

Note: The Introduction section is for your general knowledge and is not to be taken as policy coverage criteria. The rest of the policy uses specific words and concepts familiar to medical professionals. It is intended for providers. A provider can be a person, such as a doctor, nurse, psychologist, or dentist. A provider also can be a place where medical care is given, like a hospital, clinic, or lab. This policy informs them about when a service may be covered.

Policy Coverage Criteria

Service	Investigational
Peroral endoscopic myotomy	**Peroral endoscopic myotomy (POEM) is considered investigational as a treatment for pediatric and adult esophageal achalasia.** **Gastric peroral endoscopic myotomy is considered investigational as a treatment for gastroparesis.** **Note:** This policy addresses POEM. A similar acronym, POEMS syndrome, describes a different condition and is addressed in a separate medical policy. Please see **Related Policies.**

Coding

Code	Description
CPT	
43497	Lower esophageal myotomy, transoral (i.e., peroral endoscopic myotomy [POEM])
43499	Unlisted procedure, esophagus (use for G-POEM)

Note: CPT codes, descriptions and materials are copyrighted by the American Medical Association (AMA). HCPCS codes, descriptions and materials are copyrighted by Centers for Medicare Services (CMS).

Related Information

N/A

Evidence Review

Description

Esophageal achalasia is characterized by reduced numbers of neurons in the esophageal myenteric plexuses and reduced peristaltic activity, making it difficult for individuals 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 (LES). 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.

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 individuals 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 US, and the incidence of 10.5 per 100,000 person-years, with increased rates reported with more advanced age.[1]

Treatment

Treatment options for achalasia have included pharmacotherapy (e.g., injections with botulinum toxin), pneumatic dilation, and laparoscopic Heller myotomy.[2,3] 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.[3] One-year response rates of 86% and major mucosal tear rates requiring the subsequent intervention of 0.6% have been reported.[4]

POEM is a novel endoscopic procedure developed in Japan.[3,5] This procedure is performed with the individual under general anesthesia.[5] After tunneling an endoscope down the esophagus toward the esophageal-gastric junction, a surgeon performs the myotomy by cutting only the inner, circular LES muscles through a submucosal tunnel created in the proximal esophageal

mucosa. POEM differs from laparoscopic surgery, which involves complete division of both circular and longitudinal LES muscle layers. Cutting the dysfunctional muscle fibers that prevent the LES from opening allows food to enter the stomach more easily.[3,6]

NOTE: The acronym POEM in this policy refers to peroral endoscopic myotomy. POEMS syndrome, which uses a similar acronym, is discussed in a separate medical policy (see **Related Policies**).

Gastroparesis

Gastroparesis is characterized by symptoms of nausea, vomiting, bloating, early satiety, and pain, which is caused by delayed gastric emptying without mechanical obstruction.[7] The estimated US prevalence of difficult to ascertain due to the weak correlation of symptoms with gastric emptying which results in a high rate of underdiagnosis. 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.[8]

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 (e.g., 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.[7] 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.

Summary of Evidence

For adults who have achalasia who receive POEM, the evidence includes systematic reviews of primarily observational studies, four randomized controlled trials (RCTs), and nonrandomized comparative studies. Relevant outcomes are symptoms, functional outcomes, health status

measures, resource utilization, and treatment-related morbidity. Compared with pneumatic dilation (PD) or laparoscopic Heller myotomy (LHM), findings from RCTs demonstrated that POEM had a similar or greater treatment success rate based on the Eckardt score and similar or fewer overall adverse event rates. However, POEM had significantly higher rates of endoscopically confirmed reflux esophagitis and more daily proton-pump inhibitor use at 24 months. An important conduct limitation of the RCTs is that blinded assessment of outcomes was not used. Given that the primary outcome was based on subjective patient report of symptoms, this is a potential source of bias. Additionally, a potential relevance limitation is that the RCTs did not include any US sites. The comparative observational studies have primarily reported similar outcomes for POEM and for laparoscopic 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. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For pediatric individuals who have achalasia who receive POEM, the evidence includes several nonrandomized studies and two systematic reviews. 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 LES pressure. No RCTs have been reported. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For adults who have gastroparesis who receive gastric POEM (G-POEM), the evidence includes two meta-analyses, two RCTs, 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 one year to 75% at three 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.

Ongoing and Unpublished Clinical Trials

Some currently ongoing and unpublished trials that might influence this review are listed in **Table 1**.

Table 1. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
Ongoing			
NCT01793922	A Prospective Randomized Multi-center Study Comparing Endoscopic Pneumodilation and Per Oral Endoscopic Myotomy (POEM) as Treatment of Idiopathic Achalasia	150	Jan 2025
NCT04434781	Gastric Per-Oral Endoscopic Myotomy (G-POEM) for the Treatment of Gastroparesis: A Database Repository	75	Aug 2024
NCT05830994	Randomized Sham-controlled Trial Investigating Efficacy of Gastric Peroral Endoscopic Myotomy in Treatment of Diabetic Gastroparesis	20	Jun 2025
NCT04869670	A Pilot and Feasibility Trial of G-POEM for Gastroparesis to Assess Safety, Physiological Mechanisms and Efficacy	30	Jun 2025
NCT02518542	Per Oral Endoscopic Myotomy (POEM) and Prolonged Dilatation (PRD) as Additional Endoscopic Treatment Options for Achalasia and Other Esophageal Motility Disorders	400	Jun 2027
Unpublished			
NCT01601678	Endoscopic Versus Laparoscopic Myotomy for Treatment of Idiopathic Achalasia: A Randomized, Controlled Trial	240	May 2023 (last update posted June 2023)
NCT01832779	Prospective Evaluation of the Clinical Utility of Peroral Endoscopic Myotomy (POEM)	143	May 2024 (last update posted May 2024)
NCT03228758	Efficacy of Anterior Versus Posterior Myotomy Approach in Peroral Endoscopic Myotomy (POEM) for the Treatment of Achalasia – a Single Operator Analysis	89	May 2019 (last update posted May 2020)

NCT: national clinical trial

Practice Guidelines and Position Statements

The purpose of the following information is to provide reference material. Inclusion does not imply endorsement or alignment with the policy conclusions.

Guidelines or position statements will be considered for inclusion if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

American College of Gastroenterology

In 2020, the American College of Gastroenterology (ACG) issued evidence-based clinical guidelines on the diagnosis and management of achalasia.[86] The quality of the evidence and the strength of recommendations were rated based on the Grading of Recommendations Assessment, Development, and Evaluation (GRADE) framework. The evidence review includes the two RCTs of POEM compared to LHM or PD. Based on their evaluation, the ACG made the following recommendations:

- "In patients with achalasia who are candidates for definite therapy, PD, LHM, and POEM are comparable effective therapies for type I or type II achalasia and POEM would be a better treatment option in those with type III achalasia.
- "We suggest that POEM or PD result in comparable symptomatic improvement in patients with types I or II achalasia." (GRADE quality=Low, Recommendation strength=Conditional)
- "We recommend that POEM and LHM result in comparable symptomatic improvement in patients with achalasia." (GRADE quality=Moderate; Recommendation strength=Strong)
- "We recommend tailored POEM or LHM for type III achalasia as a more efficacious alternative disruptive therapy at the lower esophageal sphincter compared to PD." (GRADE quality=Moderate; Recommendation strength=Strong)
- "We suggest that in patients with achalasia, POEM compared with LHM with fundoplication or PD is associated with a higher incidence of gastroesophageal reflux disease (GERD)." (GRADE quality=Moderate; Recommendation strength=Strong)
- "We suggest that POEM is a safe option in patients with achalasia who have previously undergone PD or LHM." (GRADE quality=Low; Recommendation strength=Strong)

American Gastroenterological Association Institute

In 2017, the American Gastroenterological Association (AGA) Institute published a clinical practice update on the use of POEM for the treatment of achalasia.[83] Based on the expert review, the Institute made the following recommendations:

- POEM should be performed by experienced physicians in high-volume centers (competence achieved after estimated 20 to 40 procedures).
- If expertise is available, POEM should be considered primary therapy for type III achalasia.
- If expertise is available, POEM should be considered comparable to Heller myotomy for any achalasia syndromes.
- Patients receiving POEM should be considered high risk to develop reflux esophagitis and be advised of management considerations (e.g., proton pump inhibitor therapy and/or surveillance endoscopy) prior to undergoing POEM.

In 2023, the AGA Institute issued a clinical practice update commentary regarding gastric peroral endoscopic myotomy for gastroparesis.[87] Based on an expert review the following recommendations were provided:

- Gastric POEM (G-POEM), also called peroral endoscopic pyloromyotomy, should be considered for patients with medically refractory gastroparesis
    - Have undergo esophagogastroduodenoscopy to confirm no mechanical gastric outlet obstruction
    - Had a solid phase gastric emptying scan (GES) confirming delayed gastric emptying, preferably with retention >20% at 4 hours
    - Have moderate to severe symptoms including nausea and vomiting as the dominant symptoms on the gastroparesis cardinal symptom index
        - Patients who have failed gastric electrical stimulator therapy, pyloric stenting and botulinum toxin injection should be offered G-POEM but failure of these alternative therapies should not be a prerequisite.
- G-POEM should not be offered to the following patients:

    - Patients with opioid dependence should be weaned off opioids whenever possible and have their gastric emptying re-evaluated.
    - Most patients with postinfectious gastroparesis should not be offered G-POEM
- G-POEM should only be performed by interventional endoscopists with expertise or training in third-space endoscopy
- Patients should remain on a liquid diet for at least 24 hours before G-POEM to minimize residual gastric contents
- A high-definition gastroscope, with a waterjet, affixed with a clear distal cap, should be used to perform G-POEM. And a modern electrosurgical generator capable of modulating power based on tissue resistance and circuit impedance is necessary for G-POEM.

American Society of Gastrointestinal Endoscopy

In 2020, the American Society of Gastrointestinal Endoscopy (ASGE) issued an evidence-based guideline on the management of achalasia.[88] The methodologic quality of systematic reviews was assessed using the Methodological Quality of Systematic Reviews-2 (AMSTAR-2) tool and the certainty of the body of evidence was rated as very low to high based on the GRADE framework. ASGE rated the strength of individual recommendation based on the aggregate evidence quality and an assessment of the anticipated benefits and harms. ASGE used the phrase "we suggest" to indicate weaker recommendations and "we recommend" to indicate stronger recommendations. This guideline did not include either of the two available RCTs of POEM. Based on their evaluation, ASGE issued the following recommendations:

- "We suggest POEM as the preferred treatment for management of patients with type III achalasia." (Very low quality evidence)
- "In patients with failed initial myotomy (POEM or laparoscopic Heller myotomy), we suggest pneumatic dilation or redo myotomy using either the same or an alternative myotomy technique (POEM or laparoscopic Heller myotomy)." (Very low quality evidence)
- "We suggest that patients undergoing POEM are counseled regarding the increased risk of postprocedure reflux compared with PD and laparoscopic Heller myotomy. Based on patient preferences and physician expertise, postprocedure management options include objective testing for esophageal acid exposure, long-term acid suppressive therapy, and surveillance upper endoscopy." (Low quality evidence)

- We suggest that POEM and laparoscopic Heller myotomy are comparable treatment options for management of patients with achalasia types I and II, and the treatment option should be based on shared decision-making between the patient and provider." (Low quality evidence)

These 2020 ASGE guidelines were endorsed by the American Neurogastroenterology and Motility Society and the Society of American Gastrointestinal and Endoscopic Surgeons (SAGES).

International Society for Diseases of the Esophagus

In 2018, the International Society for Diseases of the Esophagus published guidelines on the diagnosis and management of achalasia.[89] The Society convened 51 experts from 11 countries, including several from the US, to systematically review evidence, assess recommendations using the GRADE system, and vote to integrate the recommendations into the guidelines (>80% approval required for inclusion). **Table 2** summarizes POEM recommendations.

Table 2. Recommendations for the Treatment of Achalasia

Recommendation	LOR	GOR
POEM is an effective therapy for achalasia both in short-term and medium-term follow-up with results comparable to Heller myotomy.	Conditional	Very low
POEM is an effective therapy for achalasia both in short-term and medium-term follow-up with results comparable to PD.	Conditional	Low
Pretreatment information on GERD, nonsurgical options (pneumatic dilation), and surgical options with lower GERD risk (Heller myotomy) should be provided to patient.	Good practice	NA
POEM is feasible and effective for symptom relief in patients previously treated with endoscopic therapies.	Conditional	Very low
POEM may be considered an option for treating recurrent symptoms after laparoscopic Heller myotomy.	Conditional	Low
Appropriate training (in vivo/in vitro animal model) and proctorship should be considered prior to a clinical program of POEM.	Good practice	NA

GERD: gastroesophageal reflux disease; GOR: grade of recommendation; LOR: level of recommendation; NA: not applicable; PD: pneumatic dilation; POEM: peroral endoscopic myotomy

Society of American Gastrointestinal and Endoscopic Surgeons

In 2020, SAGES endorsed the guideline on the management of achalasia issued by ASGE (2020) as described above.[88]

In 2021, SAGES issued its own evidence-based guidelines for the use of POEM for the treatment of achalasia.[90] The expert panel agreed on four recommendations for adults and children with achalasia. These include:

- The panel suggests that adult and pediatric patients with type I and II achalasia may be treated with either POEM or LHM based on surgeon and patient's shared decision making (conditional recommendation; very low certainty evidence).
- The panel suggests POEM over LHM for type III adult or pediatric achalasia. (expert opinion)
- The panel recommends POEM over PD in patients with achalasia (strong recommendation, moderate certainty evidence)
- For the subgroup of patients who are particularly concerned about the continued use of proton pump inhibitors post-operatively, the panel suggests that either POEM or PD can be used based on joint patient and surgeon decision-making (conditional recommendation, very low certainty evidence)

Medicare National Coverage

There is no national coverage determination.

Regulatory Status

POEM or G-POEM uses available laparoscopic instrumentation and, as a surgical procedure, is not subject to regulation by the US Food and Drug Administration.

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History

Date	Comments
11/11/13	New Policy. Policy created with literature search through August 1, 2013; considered investigational.
11/20/14	Annual Review. Policy updated with literature review through August 18, 2014; references 3, 6-7, 9-12, and 18 added; no change to policy statement. ICD-9 and ICD-10 diagnosis codes removed; these do not relate to adjudication of this policy.
12/08/15	Annual Review. Policy updated with literature review through October 15, 2015; references 8-11 and 23 added. Policy statement unchanged.
12/01/16	Annual Review, approved November 8, 2016. Policy reviewed with literature search through September 2016; No change to policy statement
02/01/17	Annual Review, approved January 10, 2017. Policy updated with literature review through October 10, 2016; references 6-8, 10-11, and 15-16 added. Policy statement unchanged.
11/10/17	Policy moved to new format, no changes to policy statement.

Date	Comments
02/01/18	Annual Review, approved January 9, 2018. Policy updated with literature review through September 14, 2017; reference 28 added. Policy statement unchanged.
02/01/19	Annual Review, approved January 4, 2019. Policy updated with literature review through September 2018; reference 9, 19, 30, and 34 added. Policy statement unchanged.
02/01/20	Annual Review, approved January 9, 2020. Policy updated with literature review through September 2019; references added. Policy statement clarified; for pediatric and adult esophageal achalasia; intent unchanged.
02/01/21	Annual review, approved January 6, 2021. Policy updated with literature review through September 15, 2020; references added. Policy statement unchanged.
01/01/22	Coding update. Added new CPT code 43497, removed CPT code 43499.
02/01/22	Annual review, approved January 24, 2022. Policy updated with literature review through September 25, 2021; references added. Policy statement unchanged.
02/01/23	Annual Review, approved January 9, 2023. Policy updated with literature review through August 15, 2022; no references added; Policy statement unchanged. Changed the wording from "patient" to "individual" throughout the policy for standardization. Removed new code date from 43497.
02/01/24	Annual Review, approved January 9, 2024. Policy title changed from "Peroral Endoscopic Myotomy for Treatment of Esophageal Achalasia" to" Peroral Endoscopic Myotomy for Treatment of Esophageal Achalasia and Gastroparesis". Policy updated with literature review through September 21, 2023; references added. New investigational policy statement added for use in gastroparesis. Previous policy statement unchanged. Added HCPCS code 43499 back to policy.
02/01/25	Annual Review, approved January 13, 2025. Policy updated with literature review through September 12, 2024; references added; Policy statements unchanged.

Scope: Medical policies are systematically developed guidelines that serve as a resource for Company staff when determining coverage for specific medical procedures, drugs or devices. Coverage for medical services is subject to the limits and conditions of the member benefit plan. Members and their providers should consult the member benefit booklet or contact a customer service representative to determine whether there are any benefit limitations applicable to this service or supply. This medical policy does not apply to Medicare Advantage.