BlueCross BlueShield Federal Employee Program.

FEP Medical Policy Manual

FEP 2.01.91 Peroral Endoscopic Myotomy for Treatment of Esophageal Achalasia and Gastroparesis

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Related Policies:

7.01.137 - Magnetic Esophageal Sphincter Augmentation to Treat Gastroesophageal Reflux Disease

Peroral Endoscopic Myotomy for Treatment of Esophageal Achalasia and Gastroparesis

Description

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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.

OBJECTIVE

The objective of this evidence review is to determine whether peroral endoscopic myotomy improves the net health outcome in individuals with esophageal achalasia.

POLICY STATEMENT

Peroral endoscopic myotomy is considered **investigational** as a treatment for pediatric and adult esophageal achalasia.

Gastric peroral endoscopic myotomy is considered **investigational** as a treatment for gastroparesis.

POLICY GUIDELINES

None

BENEFIT APPLICATION

Experimental or investigational procedures, treatments, drugs, or devices are not covered (See General Exclusion Section of brochure).

FDA 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.

RATIONALE

Summary of Evidence

For adults who have achalasia who receive peroral endoscopic myotomy (POEM) , the evidence includes systematic reviews of primarily observational studies, 4 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 LHM 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 4 systematic reviews. 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 (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 2 meta-analyses, 2 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 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.

SUPPLEMENTAL INFORMATION

Practice Guidelines and Position Statements

Guidelines or position statements will be considered for inclusion in 'Supplemental Information" 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.[91,] 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 2 randomized controlled trials (RCTs) of peroral endoscopic myotomy (POEM) compared to laparoscopic Heller myotomy (LHM) or pneumatic dilation (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 GERD [gastroesophageal reflux disease]." (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)

In 2022, the ACG issued evidence-based guidelines on gastroparesis.[92,]The guideline states that the efficacy of gastric POEM (G-POEM) is based on observational studies and that "overall, these open-label studies suggest there is benefit in terms of symptom improvement and improved GE [gastric emptying], though most studies were of only 3 to 6 months" duration."

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.[88,] 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 an 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 (eg, proton pump inhibitor therapy and/or surveillance endoscopy) prior to undergoing POEM.

In 2024, AGA published an expert review that acted as a clinical practice update on advances in POEM.[93,] Related to achalasia, the following best practice statements were made:

- POEM, laparoscopic Heller myotomy, and pneumatic dilation are effective therapies for type I and type II achalasia; the decision between these treatment modalities should be based on shared decision making, taking into account patient and disease characteristics, patient preferences, and local expertise. POEM should be considered the preferred treatment for type III achalasia.
- All patients should undergo monitoring for gastroesophageal reflux disease (GERD) after POEM. Patients with persistent esophagitis and/or reflux-like symptoms despite proton pump inhibitor use, should undergo additional testing to evaluate for other etiologies besides pathologic acid exposure and management to optimize and achieve reflux control.

- Long-term postprocedure surveillance is encouraged to monitor for progression of disease and complications of gastroesophageal reflux disease.
- POEM may be superior to pneumatic dilation for patients with failed initial POEM or laparoscopic Heller myotomy; however, the decision among treatment modalities should be based on shared decision making between the patient and physician, taking into account risk of postprocedural reflux, need for repeat interventions, patient preferences, and local expertise.

In 2023, the AGA Institute issued a clinical practice update commentary regarding gastric peroral endoscopic myotomy for gastroparesis.[94,] Based on an expert review the following recommendations were provided:

- G-POEM , also called peroral endoscopic pyloromyotomy, should be considered for patients with medically refractory gastroparesis who
    - 1) Have undergone esophagogastroduodenoscopy to confirm no mechanical gastric outlet obstruction
    - 2) had a solid phase gastric emptying scan (GES) confirming delayed gastric emptying, preferably with retention >20% at 4 hours
    - 3) 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 alternatives 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.

In 2025, AGA issued a clinical practice guideline on the management of gastroparesis.[95,] Related to G-POEM, the authors stated that in patients with gastroparesis refractory to medical therapy, they suggest against the routine use of G-POEM (strength of recommendation: conditional, certainty of evidence: low). As caveats to this recommendation, they state that patients and clinicians who place a higher value on the potential improvement in symptoms and lower value on the potential risk of adverse events may reasonably select to undergo G-POEM. The considerations they state should be incorporated into decision making are the same as those made in the expert commentary in 2023.

American Society of Gastrointestinal Endoscopy

In 2020, the American Society of Gastrointestinal Endoscopy (ASGE) issued an evidence-based guideline on the management of achalasia.[96,] 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 recommendations 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 2 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 PD 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.[97,] The Society convened 51 experts from 11 countries, including several from the U.S., 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 16 summarizes POEM recommendations.

Table 1. Recommendations for the Treatment of Achalasia

Recommendation	LOR	GOR
POEM is an effective therapy for achalasia both in short- and medium-term follow-up with results comparable to Heller myotomy.	Conditional	Very low
POEM is an effective therapy for achalasia both in short- and medium-term follow-up with results comparable to PD.	Conditional	Low
Pretreatment information on GERD, nonsurgical options (PD), and surgical options with lower GERD risk (Heller myotomy) should be provided to the 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.[96,]

In 2021, SAGES issued its own evidence-based guidelines for the use of POEM for the treatment of achalasia.[98,] The expert panel agreed on 4 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 (PPIs) 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)

An update to these guidelines was released in 2024.[99,] The following recommendations were made within the guideline:

- "The Guideline panel suggests that adult patients with type I and II achalasia may be treated with either POEM with appropriate use of PPI or laparoscopic Heller myotomy with fundoplication based on surgeon and patient shared decision-making. (conditional recommendation, low certainty of evidence).

- The panel suggests POEM over laparoscopic Heller myotomy for type III adult achalasia. (expert opinion).
- The panel suggests consideration of routine upper endoscopy in both groups to detect the possibility of the asymptomatic patient with significant reflux who could be at risk of adenocarcinoma. The panel also notes an absence of data on this topic and emphasizes the importance of further research to determine exact timing and protocols. The symptomatic patient should undergo appropriate work-up for objective diagnosis of GERD before treatment. (expert opinion).
- The Guideline panel suggests Peroral endoscopic myotomy over pneumatic dilatation (conditional recommendation, moderate certainty of evidence)."

U.S. Preventive Services Task Force Recommendations

Not applicable.

Medicare National Coverage

There is no national coverage determination. In the absence of a national coverage determination, coverage decisions are left to the discretion of local Medicare carriers.

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POLICY HISTORY - THIS POLICY WAS APPROVED BY THE FEP® PHARMACY AND MEDICAL POLICY COMMITTEE ACCORDING TO THE HISTORY BELOW:

Date	Action	Description
December 2013	New policy	
December 2014	Replace policy	Policy updated with literature review; references 3, 6-7, 9- 12, and 18 added. No change to policy statement.
June 2016	Replace policy	Policy updated with literature review through October 15, 2015; references 8-11 and 23 added. Policy statement unchanged.
March 2017	Replace policy	Policy updated with literature review; references 6-8, 10-11, and 15-16 added. Policy statement unchanged.
March 2018	Replace policy	Policy updated with literature review through September 14, 2017; reference 28 added. Policy statement unchanged.
March 2019	Replace policy	Policy updated with literature review through September 4, 2018; reference 9, 19, 30, and 34 added. Policy statement unchanged.

Date	Action	Description
March 2020	Replace policy	Policy updated with literature review through September 9, 2019; references added. Pediatric and adult wording added to policy statement edited for consistency; intent of statement unchanged.
March 2021	Replace policy	Policy updated with literature review through September 15, 2020; references added. Policy statement unchanged.
March 2022	Replace policy	Policy updated with literature review through September 25, 2021; references added. Policy statement unchanged.
March 2023	Replace policy	Policy updated with literature review through August 15, 2022; no references added; Policy statement unchanged.
March 2024	Replace policy	Policy updated with literature review through September 21, 2023; references added. New investigational policy statement added for use in gastroparesis. Previous policy statement unchanged.
March 2025	Replace policy	Policy updated with literature review through September 12, 2024; references added; Policy statements unchanged.
March 2026	Replace policy	Policy updated with literature review through September 23, 2025; references added. Policy statements unchanged.