



## FEP Medical Policy Manual

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

**Annual Effective Policy Date: April 1, 2024**

**Original Policy Date: December 2013**

#### **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

#### Description

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 (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 3 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, 1 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 60.7% at 1 year to 75% at 3 years in the meta-analyses. One RCT comparing G-POEM to sham was identified which found greater rates of treatment success and gastric retention at 6 months follow-up in the G-POEM group. Both the RCT and the largest observational study found the greatest treatment effect in patients who had a diabetic etiology for gastroparesis. 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.<sup>83</sup> 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)

#### American Gastroenterological Association Institute

In 2017, the American Gastroenterological Association Institute published a clinical practice update on the use of POEM for the treatment of achalasia.<sup>81</sup> 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 2023, the American Gastroenterological Association Institute issued a clinical practice update commentary regarding gastric peroral endoscopic myotomy for gastroparesis.<sup>84</sup> 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
  - 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

- o 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:
  - o Patients with opioid dependence should be weaned off opioids whenever possible and have their gastric emptying re-evaluated.
  - o 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 and Endoscopic Surgeons

In 2020, the American Society of Gastrointestinal and Endoscopic Surgeons (ASGE) issued an evidence-based guideline on the management of achalasia.<sup>84</sup> 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.<sup>85</sup> 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 1 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.<sup>84</sup>

In 2021, SAGES issued its own evidence-based guidelines for the use of POEM for the treatment of achalasia.<sup>86</sup> 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 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)

## 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.

## REFERENCES

1. Cheatham JG, Wong RK. Current approach to the treatment of achalasia. *Curr Gastroenterol Rep*. Jun 2011; 13(3): 219-25. PMID 21424734
2. Pandolfino JE, Kahrilas PJ. Presentation, diagnosis, and management of achalasia. *Clin Gastroenterol Hepatol*. Aug 2013; 11(8): 887-97. PMID 23395699
3. Yaghoobi M, Mayrand S, Martel M, et al. Laparoscopic Heller's myotomy versus pneumatic dilation in the treatment of idiopathic achalasia: a meta-analysis of randomized, controlled trials. *Gastrointest Endosc*. Sep 2013; 78(3): 468-75. PMID 23684149
4. Inoue H, Minami H, Kobayashi Y, et al. Peroral endoscopic myotomy (POEM) for esophageal achalasia. *Endoscopy*. Apr 2010; 42(4): 265-71. PMID 20354937
5. Hungness ES, Teitelbaum EN, Santos BF, et al. Comparison of perioperative outcomes between peroral esophageal myotomy (POEM) and laparoscopic Heller myotomy. *J Gastrointest Surg*. Feb 2013; 17(2): 228-35. PMID 23054897
6. Reddivari AKR, Mehta P. Gastroparesis. [Updated 2022 Sep 30]. In: *StatPearls* [Internet]. Treasure Island (FL): StatPearls Publishing; 2023 Jan-. Available from: <https://www.ncbi.nlm.nih.gov/books/NBK551528/>
7. Eckardt AJ, Eckardt VF. Treatment and surveillance strategies in achalasia: an update. *Nat Rev Gastroenterol Hepatol*. Jun 2011; 8(6): 311-9. PMID 21522116
8. Li H, Peng W, Huang S, et al. The 2 years' long-term efficacy and safety of peroral endoscopic myotomy for the treatment of achalasia: a systematic review. *J Cardiothorac Surg*. Jan 03 2019; 14(1): 1. PMID 30606216
9. Crespín OM, Liu LWC, Parmar A, et al. Safety and efficacy of POEM for treatment of achalasia: a systematic review of the literature. *Surg Endosc*. May 2017; 31(5): 2187-2201. PMID 27633440
10. Akintoye E, Kumar N, Obaitan I, et al. Peroral endoscopic myotomy: a meta-analysis. *Endoscopy*. Dec 2016; 48(12): 1059-1068. PMID 27617421
11. Patel K, Abbassi-Ghadi N, Markar S, et al. Peroral endoscopic myotomy for the treatment of esophageal achalasia: systematic review and pooled analysis. *Dis Esophagus*. Oct 2016; 29(7): 807-819. PMID 26175119
12. Andolfi C, Fisichella PM. Meta-analysis of clinical outcome after treatment for achalasia based on manometric subtypes. *Br J Surg*. Mar 2019; 106(4): 332-341. PMID 30690706
13. Dirks RC, Kohn GP, Slater B, et al. Is peroral endoscopic myotomy (POEM) more effective than pneumatic dilation and Heller myotomy? A systematic review and meta-analysis. *Surg Endosc*. May 2021; 35(5): 1949-1962. PMID 33655443
14. Facciorusso A, Singh S, Abbas Fehmi SM, et al. Comparative efficacy of first-line therapeutic interventions for achalasia: a systematic review and network meta-analysis. *Surg Endosc*. Aug 2021; 35(8): 4305-4314. PMID 32856150
15. Martins RK, Ribeiro IB, DE Moura DTH, et al. PERORAL (POEM) OR SURGICAL MYOTOMY FOR THE TREATMENT OF ACHALASIA: A SYSTEMATIC REVIEW AND META-ANALYSIS. *Arq Gastroenterol*. 2020; 57(1): 79-86. PMID 32294740
16. Aiolfi A, Bona D, Riva CG, et al. Systematic Review and Bayesian Network Meta-Analysis Comparing Laparoscopic Heller Myotomy, Pneumatic Dilation, and Peroral Endoscopic Myotomy for Esophageal Achalasia. *J Laparoendosc Adv Surg Tech A*. Feb 2020; 30(2): 147-155. PMID 31364910
17. Teitelbaum EN, Soper NJ, Santos BF, et al. Symptomatic and physiologic outcomes one year after peroral esophageal myotomy (POEM) for treatment of achalasia. *Surg Endosc*. Dec 2014; 28(12): 3359-65. PMID 24939164
18. Ujiki MB, Yetasook AK, Zapf M, et al. Peroral endoscopic myotomy: A short-term comparison with the standard laparoscopic approach. *Surgery*. Oct 2013; 154(4): 893-7; discussion 897-900. PMID 24074429
19. Bhayani NH, Kurian AA, Dunst CM, et al. A comparative study on comprehensive, objective outcomes of laparoscopic Heller myotomy with peroral endoscopic myotomy (POEM) for achalasia. *Ann Surg*. Jun 2014; 259(6): 1098-103. PMID 24169175
20. Kumagai K, Tsai JA, Thorell A, et al. Per-oral endoscopic myotomy for achalasia. Are results comparable to laparoscopic Heller myotomy?. *Scand J Gastroenterol*. May 2015; 50(5): 505-12. PMID 25712228
21. Kumbhari V, Tieu AH, Onimaru M, et al. Peroral endoscopic myotomy (POEM) vs laparoscopic Heller myotomy (LHM) for the treatment of Type III achalasia in 75 patients: a multicenter comparative study. *Endosc Int Open*. Jun 2015; 3(3): E195-201. PMID 26171430
22. Chan SM, Wu JC, Teoh AY, et al. Comparison of early outcomes and quality of life after laparoscopic Heller's cardiomyotomy to peroral endoscopic myotomy for treatment of achalasia. *Dig Endosc*. Jan 2016; 28(1): 27-32. PMID 26108140
23. Sanaka MR, Hayat U, Thota PN, et al. Efficacy of peroral endoscopic myotomy vs other achalasia treatments in improving esophageal function. *World J Gastroenterol*. May 28 2016; 22(20): 4918-25. PMID 27239118
24. Schneider AM, Louie BE, Warren HF, et al. A Matched Comparison of Per Oral Endoscopic Myotomy to Laparoscopic Heller Myotomy in the Treatment of Achalasia. *J Gastrointest Surg*. Nov 2016; 20(11): 1789-1796. PMID 27514392
25. Khashab MA, Kumbhari V, Tieu AH, et al. Peroral endoscopic myotomy achieves similar clinical response but incurs lesser charges compared to robotic heller myotomy. *Saudi J Gastroenterol*. 2017; 23(2): 91-96. PMID 28361839
26. Leeds SG, Burdick JS, Ogola GO, et al. Comparison of outcomes of laparoscopic Heller myotomy versus per-oral endoscopic myotomy for management of achalasia. *Proc (Bayl Univ Med Cent)*. Oct 2017; 30(4): 419-423. PMID 28966450
27. de Pascale S, Repici A, Puccetti F, et al. Peroral endoscopic myotomy versus surgical myotomy for primary achalasia: single-center, retrospective analysis of 74 patients. *Dis Esophagus*. Aug 01 2017; 30(8): 1-7. PMID 28575245
28. Peng L, Tian S, Du C, et al. Outcome of Peroral Endoscopic Myotomy (POEM) for Treating Achalasia Compared With Laparoscopic Heller Myotomy (LHM). *Surg Laparosc Endosc Percutan Tech*. Feb 2017; 27(1): 60-64. PMID 28145968
29. Ward MA, Gitelis M, Patel L, et al. Outcomes in patients with over 1-year follow-up after peroral endoscopic myotomy (POEM). *Surg Endosc*. Apr 2017; 31(4): 1550-1557. PMID 27858209

30. Hanna AN, Datta J, Ginzberg S, et al. Laparoscopic Heller Myotomy vs Per Oral Endoscopic Myotomy: Patient-Reported Outcomes at a Single Institution. *J Am Coll Surg*. Apr 2018; 226(4): 465-472.e1. PMID 29410262
31. Ramirez M, Zubieta C, Ciotola F, et al. Per oral endoscopic myotomy vs. laparoscopic Heller myotomy, does gastric extension length matter?. *Surg Endosc*. Jan 2018; 32(1): 282-288. PMID 28660419
32. Caldaro T, Familiari P, Romeo EF, et al. Treatment of esophageal achalasia in children: Today and tomorrow. *J Pediatr Surg*. May 2015; 50(5): 726-30. PMID 25783358
33. Fumagalli U, Rosati R, De Pascale S, et al. Repeated Surgical or Endoscopic Myotomy for Recurrent Dysphagia in Patients After Previous Myotomy for Achalasia. *J Gastrointest Surg*. Mar 2016; 20(3): 494-9. PMID 26589525
34. Greenleaf EK, Winder JS, Hollenbeak CS, et al. Cost-effectiveness of per oral endoscopic myotomy relative to laparoscopic Heller myotomy for the treatment of achalasia. *Surg Endosc*. Jan 2018; 32(1): 39-45. PMID 29218664
35. Kim GH, Jung KW, Jung HY, et al. Superior clinical outcomes of peroral endoscopic myotomy compared with balloon dilation in all achalasia subtypes. *J Gastroenterol Hepatol*. Apr 2019; 34(4): 659-665. PMID 30695124
36. Meng F, Li P, Wang Y, et al. Peroral endoscopic myotomy compared with pneumatic dilation for newly diagnosed achalasia. *Surg Endosc*. Nov 2017; 31(11): 4665-4672. PMID 28411346
37. Miller HJ, Neupane R, Fayeizadeh M, et al. POEM is a cost-effective procedure: cost-utility analysis of endoscopic and surgical treatment options in the management of achalasia. *Surg Endosc*. Apr 2017; 31(4): 1636-1642. PMID 27534662
38. Ponds FA, Fockens P, Lei A, et al. Effect of Peroral Endoscopic Myotomy vs Pneumatic Dilation on Symptom Severity and Treatment Outcomes Among Treatment-Naive Patients With Achalasia: A Randomized Clinical Trial. *JAMA*. Jul 09 2019; 322(2): 134-144. PMID 31287522
39. Sanaka MR, Thota PN, Parikh MP, et al. Peroral endoscopic myotomy leads to higher rates of abnormal esophageal acid exposure than laparoscopic Heller myotomy in achalasia. *Surg Endosc*. Jul 2019; 33(7): 2284-2292. PMID 30341655
40. Wang X, Tan Y, Lv L, et al. Peroral endoscopic myotomy versus pneumatic dilation for achalasia in patients aged  $\geq 65$  years. *Rev Esp Enferm Dig*. Oct 2016; 108(10): 637-641. PMID 27649684
41. Werner YB, Hakanson B, Martinek J, et al. Endoscopic or Surgical Myotomy in Patients with Idiopathic Achalasia. *N Engl J Med*. Dec 05 2019; 381(23): 2219-2229. PMID 31800987
42. Wirsching A, Boshier PR, Klevebro F, et al. Comparison of costs and short-term clinical outcomes of per-oral endoscopic myotomy and laparoscopic Heller myotomy. *Am J Surg*. Oct 2019; 218(4): 706-711. PMID 31353034
43. Zheng Z, Zhao C, Su S, et al. Peroral endoscopic myotomy versus pneumatic dilation - result from a retrospective study with 1-year follow-up. *Z Gastroenterol*. Mar 2019; 57(3): 304-311. PMID 30861554
44. Podboy AJ, Hwang JH, Rivas H, et al. Long-term outcomes of per-oral endoscopic myotomy compared to laparoscopic Heller myotomy for achalasia: a single-center experience. *Surg Endosc*. Feb 2021; 35(2): 792-801. PMID 32157405
45. Tan Y, Zhu H, Li C, et al. Comparison of peroral endoscopic myotomy and endoscopic balloon dilation for primary treatment of pediatric achalasia. *J Pediatr Surg*. Oct 2016; 51(10): 1613-8. PMID 27339081
46. Boeckstaens GE, Annese V, des Varannes SB, et al. Pneumatic dilation versus laparoscopic Heller's myotomy for idiopathic achalasia. *N Engl J Med*. May 12 2011; 364(19): 1807-16. PMID 21561346
47. Borges AA, Lemme EM, Abrahao LJ, et al. Pneumatic dilation versus laparoscopic Heller myotomy for the treatment of achalasia: variables related to a good response. *Dis Esophagus*. Jan 2014; 27(1): 18-23. PMID 23551592
48. Kostic S, Kjellin A, Ruth M, et al. Pneumatic dilatation or laparoscopic cardiomyotomy in the management of newly diagnosed idiopathic achalasia. Results of a randomized controlled trial. *World J Surg*. Mar 2007; 31(3): 470-8. PMID 17308851
49. Hamdy E, El Nakeeb A, El Hanfy E, et al. Comparative Study Between Laparoscopic Heller Myotomy Versus Pneumatic Dilatation for Treatment of Early Achalasia: A Prospective Randomized Study. *J Laparoendosc Adv Surg Tech A*. Jun 2015; 25(6): 460-4. PMID 25951417
50. Zhong C, Tan S, Huang S, et al. Peroral endoscopic myotomy versus pneumatic dilation for achalasia: a systematic review and meta-analysis. *Eur J Gastroenterol Hepatol*. Nov 2020; 32(11): 1413-1421. PMID 32516175
51. de Moura ETH, Jukemura J, Ribeiro IB, et al. Peroral endoscopic myotomy vs laparoscopic myotomy and partial fundoplication for esophageal achalasia: A single-center randomized controlled trial. *World J Gastroenterol*. Sep 07 2022; 28(33): 4875-4889. PMID 36156932
52. Saleh CMG, Familiari P, Bastiaansen BAJ, et al. The Efficacy of Peroral Endoscopic Myotomy vs Pneumatic Dilation as Treatment for Patients With Achalasia Suffering From Persistent or Recurrent Symptoms After Laparoscopic Heller Myotomy: A Randomized Clinical Trial. *Gastroenterology*. Jun 2023; 164(7): 1108-1118.e3. PMID 36907524
53. Kuipers T, Ponds FA, Fockens P, et al. Peroral endoscopic myotomy versus pneumatic dilation in treatment-naive patients with achalasia: 5-year follow-up of a randomised controlled trial. *Lancet Gastroenterol Hepatol*. Dec 2022; 7(12): 1103-1111. PMID 36206786
54. Docimo S, Mathew A, Shope AJ, et al. Reduced postoperative pain scores and narcotic use favor per-oral endoscopic myotomy over laparoscopic Heller myotomy. *Surg Endosc*. Feb 2017; 31(2): 795-800. PMID 27338580
55. Haseeb M, Khan Z, Kamal MU, et al. Short-term outcomes after peroral endoscopic myotomy, Heller myotomy, and pneumatic dilation in patients with achalasia: a nationwide analysis. *Gastrointest Endosc*. May 2023; 97(5): 871-879.e2. PMID 36639060
56. Shally L, Saeed K, Berglund D, et al. Clinical and financial outcomes of per-oral endoscopic myotomy compared to laparoscopic heller myotomy for treatment of achalasia. *Surg Endosc*. Jul 2023; 37(7): 5526-5537. PMID 36220985
57. Nabi Z, Talukdar R, Chavan R, et al. Outcomes of Per-Oral Endoscopic Myotomy in Children: A Systematic Review and Meta-analysis. *Dysphagia*. Dec 2022; 37(6): 1468-1481. PMID 35092485
58. Zhong C, Tan S, Huang S, et al. Clinical outcomes of peroral endoscopic myotomy for achalasia in children: a systematic review and meta-analysis. *Dis Esophagus*. Apr 07 2021; 34(4). PMID 33316041
59. Lee Y, Brar K, Doumouras AG, et al. Peroral endoscopic myotomy (POEM) for the treatment of pediatric achalasia: a systematic review and meta-analysis. *Surg Endosc*. Jun 2019; 33(6): 1710-1720. PMID 30767141

60. Bi YW, Lei X, Ru N, et al. Per-oral endoscopic myotomy is safe and effective for pediatric patients with achalasia: A long-term follow-up study. *World J Gastroenterol*. Jun 14 2023; 29(22): 3497-3507. PMID 37389239
61. Petrosyan M, Mostamand S, Shah AA, et al. Per Oral Endoscopic Myotomy (POEM) for pediatric achalasia: Institutional experience and outcomes. *J Pediatr Surg*. Nov 2022; 57(11): 728-735. PMID 35361482
62. Nabi Z, Ramchandani M, Chavan R, et al. Outcome of peroral endoscopic myotomy in children with achalasia. *Surg Endosc*. Nov 2019; 33(11): 3656-3664. PMID 30671667
63. Miao S, Wu J, Lu J, et al. Peroral Endoscopic Myotomy in Children With Achalasia: A Relatively Long-term Single-center Study. *J Pediatr Gastroenterol Nutr*. Feb 2018; 66(2): 257-262. PMID 28691974
64. Revicki DA, Rentz AM, Dubois D, et al. Gastroparesis Cardinal Symptom Index (GCSI): development and validation of a patient reported assessment of severity of gastroparesis symptoms. *Qual Life Res*. May 2004; 13(4): 833-44. PMID 15129893
65. Kamal F, Khan MA, Lee-Smith W, et al. Systematic review with meta-analysis: one-year outcomes of gastric peroral endoscopic myotomy for refractory gastroparesis. *Aliment Pharmacol Ther*. Jan 2022; 55(2): 168-177. PMID 34854102
66. Canakis A., et al., Long-term outcomes (3 years) after gastric peroral endoscopic myotomy for refractory gastroparesis: a systematic review and meta-analysis. *iGIE*, 2023. 2(3): p. 344-349.e3.
67. Labonde A, Lades G, Debourdeau A, et al. Gastric peroral endoscopic myotomy in refractory gastroparesis: long-term outcomes and predictive score to improve patient selection. *Gastrointest Endosc*. Sep 2022; 96(3): 500-508.e2. PMID 35413333
68. Hernandez Mondragn OV, Contreras LFG, Velasco GB, et al. Gastric peroral endoscopic myotomy outcomes after 4 years of follow-up in a large cohort of patients with refractory gastroparesis (with video). *Gastrointest Endosc*. Sep 2022; 96(3): 487-499. PMID 35378136
69. Vosoughi K, Ichkhanian Y, Benias P, et al. Gastric per-oral endoscopic myotomy (G-POEM) for refractory gastroparesis: results from an international prospective trial. *Gut*. Jan 2022; 71(1): 25-33. PMID 33741641
70. Gregor L, Wo J, DeWitt J, et al. Gastric peroral endoscopic myotomy for the treatment of refractory gastroparesis: a prospective single-center experience with mid-term follow-up (with video). *Gastrointest Endosc*. Jul 2021; 94(1): 35-44. PMID 33373646
71. Conchillo JM, Straathof JWA, Mujagic Z, et al. Gastric peroral endoscopic pyloromyotomy for decompensated gastroparesis: comprehensive motility analysis in relation to treatment outcomes. *Endosc Int Open*. Feb 2021; 9(2): E137-E144. PMID 33532550
72. Abdelfatah MM, Noll A, Kapil N, et al. Long-term Outcome of Gastric Per-Oral Endoscopic Pyloromyotomy in Treatment of Gastroparesis. *Clin Gastroenterol Hepatol*. Apr 2021; 19(4): 816-824. PMID 32450364
73. Husťak R, Vackov Z, Krajciová J, et al. Per-oral endoscopic pyloromyotomy (g-poem) for the treatment of gastroparesis - a pilot single-centre study with mid-term follow-up. *Rozhl Chir*. 2020; 99(3): 116-123. PMID 32349495
74. Tan J, Shrestha SM, Wei M, et al. Feasibility, safety, and long-term efficacy of gastric peroral endoscopic myotomy (G-POEM) for postsurgical gastroparesis: a single-center and retrospective study of a prospective database. *Surg Endosc*. Jul 2021; 35(7): 3459-3470. PMID 32880749
75. Attaar M, Su B, Wong HJ, et al. Comparing cost and outcomes between peroral endoscopic myotomy and laparoscopic heller myotomy. *Am J Surg*. Jul 2021; 222(1): 208-213. PMID 33162014
76. Ragi O, Jacques J, Branche J, et al. One-year results of gastric peroral endoscopic myotomy for refractory gastroparesis: a French multicenter study. *Endoscopy*. May 2021; 53(5): 480-490. PMID 32575130
77. Shen S, Luo H, Vachaparambil C, et al. Gastric peroral endoscopic pyloromyotomy versus gastric electrical stimulation in the treatment of refractory gastroparesis: a propensity score-matched analysis of long term outcomes. *Endoscopy*. May 2020; 52(5): 349-358. PMID 32084672
78. Vosoughi K, Ichkhanian Y, Jacques J, et al. Role of endoscopic functional luminal imaging probe in predicting the outcome of gastric peroral endoscopic pyloromyotomy (with video). *Gastrointest Endosc*. Jun 2020; 91(6): 1289-1299. PMID 32035074
79. Xu J, Chen T, Elkholy S, et al. Gastric Peroral Endoscopic Myotomy (G-POEM) as a Treatment for Refractory Gastroparesis: Long-Term Outcomes. *Can J Gastroenterol Hepatol*. 2018; 2018: 6409698. PMID 30425974
80. Davis BR, Sarosiek I, Bashashati M, et al. The Long-Term Efficacy and Safety of Pyloroplasty Combined with Gastric Electrical Stimulation Therapy in Gastroparesis. *J Gastrointest Surg*. Feb 2017; 21(2): 222-227. PMID 27896652
81. Kahrilas PJ, Katzka D, Richter JE. Clinical Practice Update: The Use of Per-Oral Endoscopic Myotomy in Achalasia: Expert Review and Best Practice Advice From the AGA Institute. *Gastroenterology*. Nov 2017; 153(5): 1205-1211. PMID 28989059
82. Martinek J, Hustak R, Mares J, et al. Endoscopic pyloromyotomy for the treatment of severe and refractory gastroparesis: a pilot, randomised, sham-controlled trial. *Gut*. Nov 2022; 71(11): 2170-2178. PMID 35470243
83. Vaezi MF, Pandolfino JE, Yadlapati RH, et al. ACG Clinical Guidelines: Diagnosis and Management of Achalasia. *Am J Gastroenterol*. Sep 2020; 115(9): 1393-1411. PMID 32773454
84. Khashab MA, Vela MF, Thosani N, et al. ASGE guideline on the management of achalasia. *Gastrointest Endosc*. Feb 2020; 91(2): 213-227.e6. PMID 31839408
85. Zaninotto G, Bennett C, Boeckxstaens G, et al. The 2018 ISDE achalasia guidelines. *Dis Esophagus*. Sep 01 2018; 31(9). PMID 30169645
86. Kohn GP, Dirks RC, Ansari MT, et al. SAGES guidelines for the use of peroral endoscopic myotomy (POEM) for the treatment of achalasia. *Surg Endosc*. May 2021; 35(5): 1931-1948. PMID 33564964



## 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.
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.

The policies contained in the FEP Medical Policy Manual are developed to assist in administering contractual benefits and do not constitute medical advice. They are not intended to replace or substitute for the independent medical judgment of a practitioner or other health care professional in the treatment of an individual member. The Blue Cross and Blue Shield Association does not intend by the FEP Medical Policy Manual, or by any particular medical policy, to recommend, advocate, encourage or discourage any particular medical technologies. Medical decisions relative to medical technologies are to be made strictly by members/patients in consultation with their health care providers. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that the Blue Cross and Blue Shield Service Benefit Plan covers (or pays for) this service or supply for a particular member.