

## Medical Coverage Policy | Peroral Endoscopic Myotomy for Treatment of Esophageal Achalasia



**EFFECTIVE DATE:** 06|01|2020

**POLICY LAST UPDATED:** 02|03|2021

### 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.

### 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.

#### 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.

### 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. The estimated U.S. prevalence of achalasia is 10 cases per 100000, and the estimated incidence is 0.6 cases per 100000 per year.

#### 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.

### **Regulatory Status**

POEM 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**

There is not a specific code for this service. Claims must be filed with the following unlisted code 43499 Unlisted procedure, esophagus

### **RELATED POLICIES**

None

### **PUBLISHED**

Provider Update, April 2021

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### **REFERENCES:**

1. Cheatham JG, Wong RK. Current approach to the treatment of achalasia. *Curr Gastroenterol Rep.* Jun 2011;13(3):219-225. PMID 21424734.

2. Pandolfino JE, Kahrilas PJ. Presentation, diagnosis, and management of achalasia. *Clin Gastroenterol Hepatol.* Aug 2013;11(8):887-897. 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):468-475. PMID 23684149.
4. Inoue H, Minami H, Kobayashi Y, et al. Peroral endoscopic myotomy (POEM) for esophageal achalasia. *Endoscopy.* Apr 2010;42(4):265-271. 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):228-235. PMID 23054897.
6. Eckardt AJ, Eckardt VF. Treatment and surveillance strategies in achalasia: an update. *Nat Rev Gastroenterol Hepatol.* Jun 2011;8(6):311-319. PMID 21522116.
7. 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.* 2019 Jan 5;14(1). PMID 30606216.
8. Schlottmann F, Luckett DJ, Fine J et al. Laparoscopic Heller Myotomy Versus Peroral Endoscopic Myotomy (POEM) for Achalasia: A Systematic Review and Meta-analysis. *Ann. Surg.*, 2017 May 27;267(3). PMID 28549006.
9. Crespin 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. Zhang Y, Wang H, Chen X, et al. Per-oral endoscopic myotomy versus laparoscopic Heller myotomy for achalasia: a meta-analysis of nonrandomized comparative studies. *Medicine (Baltimore).* Feb 2016;95(6):e2736. PMID 26871816.
13. Bhayani NH, Kurian AA, Dunst CM, et al. A comparative study on comprehensive, objective outcomes of laparoscopic Heller myotomy with per-oral endoscopic myotomy (POEM) for achalasia. *Ann Surg.* Jun 2014;259(6):1098-1103. PMID 24169175.
14. Marano L, Pallabazzer G, Solito B, et al. Surgery or peroral esophageal myotomy for achalasia: a systematic review and meta-analysis. *Medicine (Baltimore).* Mar 2016;95(10):e3001. PMID 26962813.
15. Talukdar R, Inoue H, Nageshwar Reddy D. Efficacy of peroral endoscopic myotomy (POEM) in the treatment of achalasia: a systematic review and meta-analysis. *Surg Endosc.* 2014 Dec 30;29(11). PMID 25539695.
16. 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.* 2019 Jul 10;322(2). PMID 31287522.
17. Li QL, Wu QN, Zhang XC et al. Outcomes of per-oral endoscopic myotomy for treatment of esophageal achalasia with a median follow-up of 49 months. *Gastrointest. Endosc.*, 2017 Nov 8;87(6). PMID 29108981.
18. 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.* 2016 Jun 25;31(2). PMID 27338580.
19. 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):4918-4925. PMID 27239118.
20. 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.
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. Patti MG, Fisichella PM. Controversies in management of achalasia. *J Gastrointest Surg.* Sep 2014;18(9):1705- 1709. PMID 24972973.

23. 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):893-897; discussion 897-900. PMID 24074429.
24. Hungness ES, Sternbach JM, Teitelbaum EN et al. Per-oral Endoscopic Myotomy (POEM) After the Learning Curve: Durable Long-term Results With a Low Complication Rate. *Ann. Surg.*, 2016 Aug 12;264(3). PMID 27513156.
25. Ramchandani M, Nageshwar Reddy D, Darisetty S, et al. Peroral endoscopic myotomy for achalasia cardia: Treatment analysis and follow up of over 200 consecutive patients at a single center. *Dig Endosc*. Jan 2016;28(1):19-26. PMID 26018637.
26. Inoue H, Sato H, Ikeda H, et al. Per-oral endoscopic myotomy: a series of 500 patients. *J Am Coll Surg*. Aug 2015;221(2):256-264. PMID 26206634.
27. 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):3359-3365. PMID 24939164.
28. Ling T, Guo H, Zou X. Effect of peroral endoscopic myotomy in achalasia patients with failure of prior pneumatic dilation: A prospective case-control study. *J Gastroenterol Hepatol*. Aug 2014;29(8):1609-1613. PMID 24628480.
29. Ling TS, Guo HM, Yang T, et al. Effectiveness of peroral endoscopic myotomy in the treatment of achalasia: A pilot trial in Chinese Han population with a minimum of one-year follow-up. *J Dig Dis*. Jul 2014;15(7):352-358. PMID 24739072.
30. Von Renteln D, Fuchs KH, Fockens P, et al. Peroral endoscopic myotomy for the treatment of achalasia: an international prospective multicenter study. *Gastroenterology*. Aug 2013;145(2):309-311 e303. PMID 23665071.
31. Ren Z, Zhong Y, Zhou P, et al. Perioperative management and treatment for complications during and after peroral endoscopic myotomy (POEM) for esophageal achalasia (EA) (data from 119 cases). *Surg Endosc*. Nov 2012;26(11):3267-3272. PMID 22609984.
32. Onimaru M, Inoue H, Ikeda H, et al. Peroral endoscopic myotomy is a viable option for failed surgical esophagocardiomyotomy instead of redo surgical Heller myotomy: a single center prospective study. *J Am Coll Surg*. Oct 2013;217(4):598-605. PMID 23891071.
33. Zhou PH, Li QL, Yao LQ, et al. Peroral endoscopic remyotomy for failed Heller myotomy: a prospective single-center study. *Endoscopy*. Mar 2013;45(3):161-166. PMID 23389963.
34. Li QL, Chen WF, Zhou PH, et al. Peroral endoscopic myotomy for the treatment of achalasia: a clinical comparative study of endoscopic full-thickness and circular muscle myotomy. *J Am Coll Surg*. Jul 25 2013;217(3):442-451. PMID 23891074.
35. 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*, 2019 Feb 16;33(6). PMID 30767141.
36. Nabi Z, Ramchandani M, Chavan R et al. Outcome of peroral endoscopic myotomy in children with achalasia. *Surg Endosc*, 2019 Jan 24. PMID 30671667.
37. 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.*, 2017 Jul 12;66(2). PMID 28691974.
38. 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*, 2017 Oct 11;153(5). PMID 28989059.
39. Pasha SF, Acosta RD, Chandrasekhara V, et al. The role of endoscopy in the evaluation and management of dysphagia. *Gastrointest Endosc*. Feb 2014;79(2):191-201. PMID 24332405.
40. Vaezi MF, Pandolfino JE, Vela MF. ACG clinical guideline: diagnosis and management of achalasia. *Am J Gastroenterol*. Aug 2013;108(8):1238-1249; quiz 1250. PMID 23877351.
41. Stefanidis D, Richardson W, Farrell TM, et al. SAGES guidelines for the surgical treatment of esophageal achalasia. *Surg Endosc*. Feb 2012;26(2):296-311. PMID 22044977.
42. Zaninotto G, Bennett C, Boeckxstaens G et al. The 2018 ISDE achalasia guidelines. *Dis. Esophagus*, 2018 Sep 1;31(9). PMID 30169645.

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