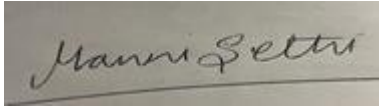


**Prior Authorization Review Panel
MCO Policy Submission**

A separate copy of this form must accompany each policy submitted for review.
Policies submitted without this form will not be considered for review.

Plan: Keystone First	Submission Date: 1/2/2025
Policy Number: ccp.1199	Effective Date: 1/2016 Revision Date: November 1, 2024
Policy Name: Peroral endoscopic myotomy	
Type of Submission – Check all that apply: <div style="margin-left: 20px;"><input type="checkbox"/> New Policy <input checked="" type="checkbox"/> Revised Policy* <input type="checkbox"/> Annual Review – No Revisions <input type="checkbox"/> Statewide PDL</div>	
*All revisions to the policy <u>must</u> be highlighted using track changes throughout the document. Please provide any clarifying information for the policy below: 	
Name of Authorized Individual (Please type or print): Manni Sethi, MD, MBA, CHCQM	Signature of Authorized Individual: 

Peroral endoscopic myotomy

Clinical Policy ID: CCP.1199

Recent review date: 11/2024

Next review date: 3/2026

Policy contains: Achalasia; dysphagia; esophageal diverticula; gastroparesis; laparoscopic Heller myotomy; peroral endoscopic myotomy; pneumatic dilation.

Keystone First has developed clinical policies to assist with making coverage determinations. Keystone First's clinical policies are based on guidelines from established industry sources, such as the Centers for Medicare & Medicaid Services (CMS), state regulatory agencies, the American Medical Association (AMA), medical specialty professional societies, and peer-reviewed professional literature. These clinical policies along with other sources, such as plan benefits and state and federal laws and regulatory requirements, including any state- or plan-specific definition of "medically necessary," and the specific facts of the particular situation are considered by Keystone First, on a case by case basis, when making coverage determinations. In the event of conflict between this clinical policy and plan benefits and/or state or federal laws and/or regulatory requirements, the plan benefits and/or state and federal laws and/or regulatory requirements shall control. Keystone First's clinical policies are for informational purposes only and not intended as medical advice or to direct treatment. Physicians and other health care providers are solely responsible for the treatment decisions for their patients. Keystone First's clinical policies are reflective of evidence-based medicine at the time of review. As medical science evolves, Keystone First will update its clinical policies as necessary. Keystone First's clinical policies are not guarantees of payment.

Coverage policy

Peroral endoscopic myotomy is clinically proven and, therefore, may be medically necessary for treatment of esophageal achalasia, when all of the following criteria are met (Society of American Gastrointestinal and Endoscopic Surgeons [Kohn, 2021]; American College of Gastroenterology [Vaezi, 2020]; International Society for Diseases of the Esophagus [Zaninotto, 2018]):

- Either treatment-naïve or recurrent/persistent achalasia following pneumatic dilation, laparoscopic Heller myotomy, or previous peroral endoscopic myotomy (Vaezi, 2020).
- Diagnosis of esophageal achalasia type I, II, or III based on high resolution manometry.

Gastric peroral endoscopic myotomy is clinically proven and, therefore, may be medically necessary for treating members ages 18 years or older with medically refractory gastroparesis, who meet all of the following criteria (American College of Gastroenterology [Camilleri, 2022]; American Gastroenterological Association [Khashab, 2023]):

- Esophagogastroduodenoscopy confirms no mechanical gastric outlet obstruction.
- Solid-phase gastric emptying scan confirms delayed gastric emptying, preferably with retention > 20% at four hours.
- Moderate-to-severe symptoms exist, preferably with nausea and vomiting as the dominant symptoms, which generally corresponds to a Gastroparesis Cardinal Symptom Index total score > 2.
- As initial treatment or following failure of gastric electrical stimulator therapy, pyloric stenting, or botulinum toxin injection.

Peroral endoscopic myotomy is investigational/not clinically proven and, therefore, not medically necessary for treatment of:

- Esophageal diverticula (Mandavdhare, 2021).
- Gastroparesis in pediatric populations (< age 18 years) (Khashab, 2023).

Limitations

Contraindications to any peroral endoscopic myotomy procedures include (Camilleri, 2022; Khashab, 2023; Kohn, 2021; Vaezi, 2020):

- Uncorrected coagulopathy.
- Presence of liver cirrhosis.
- Pregnancy at the time of treatment.
- Severe erosive esophagitis.
- Cardiac pacemaker
- Severe pulmonary disease.
- Not a candidate for an endoscopic examination or anesthesia.

Additional contraindications to peroral endoscopic myotomy for esophageal achalasia include (Vaezi, 2020):

- Diagnosis of secondary achalasia or other organic causes of dysphagia, such as esophageal varices, Barrett's esophagus, esophageal stricture, malignant or premalignant esophageal lesions, or an extremely dilated esophageal body (> 6 cm).
- Prior therapy that may compromise the integrity of the esophageal mucosa or lead to submucosal fibrosis, such as recent esophageal surgery, radiation, endoscopic mucosal resection, or radiofrequency ablation.

For gastric peroral endoscopic myotomy, additional contraindications include an absent pylorus, prior gastrointestinal surgery that alters the stomach, and postinfectious gastroparesis (Khashab, 2023).

Alternative covered services

- Open or laparoscopic esophagomyotomy with or without fundoplication.
- Endoscopically-guided pneumatic dilation.
- Botulinum toxin injection.
- Oral pharmacologics (e.g., calcium channel blockers, long-acting nitrates, anticholinergics, β -adrenergic agonists, and theophylline).
- Gastric electrical stimulator therapy.
- Pyloric stenting, surgical pyloroplasty, or partial gastrectomy.

Background

Achalasia is an esophageal motility disorder of the esophageal smooth muscle layer and the lower esophageal sphincter. Incomplete lower esophageal sphincter relaxation, increased lower esophageal sphincter pressure, and aperistalsis of the distal one-third of the esophageal body characterize the disorder (Friedel, 2013).

Achalasia is rare in the pediatric population and even less so in children younger than five years of age (Franklin, 2014). The majority of cases are idiopathic, but the disorder can be associated with malignancy (especially involving the gastro-esophageal junction) and as a part of the spectrum of Chagas disease. In rare cases, achalasia is transmitted genetically (Franklin, 2014; Friedel, 2013).

The Eckardt scoring system is most frequently used for the evaluation of symptoms, stages, and efficacy of achalasia treatment. It attributes zero to three points to each of the four symptoms of the disease (dysphagia, regurgitation, chest pain, and weight loss). Point totals range from 0 to 12, with a higher score indicating more severe symptoms. Scores of 0-1 correspond to clinical stage 0, 2-3 to stage I, 4-6 to stage II, and greater than 6 to stage III (Laurino-Neto, 2018).

The diagnostic standard for esophageal achalasia is esophageal manometry. Chicago Classification criteria based on high-resolution manometry define achalasia syndromes according to different patterns of esophageal contractility that accompany impaired esophagogastric junction (Kahrilas, 2015):

- Type I indicates 100% failed peristalsis.
- Type II, 100% failed peristalsis and panesophageal pressurization in at least 20% of swallows.
- Type III, no normal peristalsis and premature/spastic contractions in at least 20% of swallows.

Other tests include barium contrast radiography and endoscopic assessment of the gastroesophageal junction and gastric cardia, as recommended, to rule out pseudoachalasia and mechanical obstruction (Kahrilas, 2015).

Achalasia is an incurable chronic condition that requires lifelong follow up. Treatment goals are to relieve symptoms, improve esophageal emptying, and prevent further esophageal dilation. Current non-surgical treatment options are oral pharmacologic interventions, botulinum toxin injection, and pneumatic dilation. Surgical options are open or laparoscopic esophagomyotomy (also known as Heller myotomy), with or without an antireflux procedure, and esophagectomy, which is reserved for the most severe, end-stage disease. Surgical treatments aim to decrease the resting pressure in the lower esophageal sphincter, but each is associated with varying efficacy and risk. No intervention significantly affects esophageal peristalsis, but despite initial success of these interventions, lower esophageal sphincter hypertonicity returns over time, often requiring repeat interventions (Vaezi, 2020).

Peroral endoscopic myotomy is a hybrid technique derived from natural orifice transluminal endoscopic surgery and advances in endoscopic submucosal dissection to perform a myotomy. Developed in Japan, it involves an esophageal mucosal incision, followed by creation of a submucosal tunnel crossing the esophagogastric junction and myotomy before closure of the mucosal incision. Peroral endoscopic myotomy represents a novel, minimally invasive, and potentially effective endoscopic treatment for achalasia (Friedel, 2013).

Variations of the procedure have emerged to treat other esophageal conditions. Gastroparesis is a debilitating gastrointestinal disorder characterized by delayed gastric emptying in the absence of a mechanical obstruction. The condition presents a spectrum of clinical symptoms ranging from mild to severe. Several therapeutic interventions directed to the pylorus for treatment for refractory gastroparesis have been developed over the last decade but have achieved limited success. These options include intra-pyloric injections of botulinum toxin, transpyloric stenting, and surgical pyloroplasty. An application of peroral endoscopic myotomy to the pyloric valve called gastric peroral endoscopic myotomy or gastric peroral endoscopic pyloromyotomy, has emerged as a potential treatment for refractory gastroparesis (Khoury, 2018).

Esophageal diverticula are herniations of the esophagus typically resulting from an increased intraesophageal pressure or periesophageal chronic inflammation (Yam, 2024). There is emerging interest in the use of the peroral endoscopic myotomy procedure to treat esophageal diverticula, particularly Zenker's diverticula.

Findings

Guidelines

Esophageal achalasia

Current guidelines from the American College of Gastroenterology (Vaezi, 2020), the Society of American Gastrointestinal and Endoscopic Surgeons (Kohn, 2021), and the International Society for Diseases of the Esophagus (Zaninotto, 2018) support the use of peroral endoscopic myotomy in adults ages 18 and older as an effective initial treatment for type I or type II esophageal achalasia or as salvage treatment for previous endoscopic and surgical intervention, and tailored peroral endoscopic myotomy is preferred over laparoscopic Heller myotomy for type III achalasia. Vaezi (2020) also noted that repeat peroral endoscopic myotomy may be performed in those with recurrent disease who are candidates for the procedures.

The evidence supporting these recommendations consisted of cohort studies of variable quality and expert opinion. Short-term and medium-term follow-up data suggested peroral endoscopic myotomy, Heller myotomy, and pneumatic dilation offer comparable safety and symptom improvement. Peroral endoscopic myotomy is associated with a higher incidence of gastroesophageal reflux disease, and acid-suppressive therapy should be offered to manage gastroesophageal reflux disease-induced symptoms.

These recommendations extend to pediatric populations. Both the International Society for Diseases of the Esophagus and the Society of American Gastrointestinal and Endoscopic Surgeons conditionally recommend surgical or endoscopic myotomy (including peroral endoscopic myotomy) as the preferred treatment in children with idiopathic achalasia, particularly for those ages 5 years or older. The recommendation was based on very low quality evidence from case series suggesting the procedure is both safe and feasible and may provide relief of dysphagia (Kohn, 2021; Zaninotto, 2018).

Gastroparesis

The American College of Gastroenterology issued a conditional recommendation for gastric peroral endoscopic myotomy as a surgical option for patients with medically refractory gastroparesis, based on low-quality evidence from 13 open-label studies, four systematic reviews and meta-analyses, and two studies comparing pyloromyotomy to pyloroplasty. The results suggest gastric peroral endoscopic myotomy improves symptoms and gastric emptying in the short- to medium-term compared to no treatment, although results with follow-up longer than six months are needed. The authors stated that, in clinical practice, gastric peroral endoscopic myotomy has largely replaced intrapyloric botulinum toxin injection, partial gastrectomy, and pyloroplasty (Camilleri, 2022).

Similarly, the American Gastroenterological Association (Khashab, 2023) suggests considering gastric peroral endoscopic myotomy for adults with medically refractory gastroparesis in whom: 1) esophagogastroduodenoscopy confirms no mechanical gastric outlet obstruction; 2) solid-phase gastric emptying scan confirms delayed gastric emptying, preferably with retention > 20% at four hours; and 3) moderate-to-severe symptoms exist, preferably with nausea and vomiting as the dominant symptoms.

Failure of gastric electrical stimulator therapy, pyloric stenting, and botulinum toxin injection is not a prerequisite to pyloromyotomy. Notably, a significant minority of patients will not achieve a clinically satisfactory response following gastric peroral endoscopic myotomy. Repeated gastric peroral endoscopic myotomy can be very challenging due to dense fibrosis created from the first procedure, and salvage strategies are lacking. There is insufficient published evidence to comment on the safety and efficacy of performing gastric peroral endoscopic myotomy for children with gastroparesis (Khashab, 2023).

Evidence reviews

Achalasia

The evidence from systematic reviews and meta-analyses consists of observational studies and three small randomized controlled trials comparing peroral endoscopic myotomy to Heller myotomy (with fundoplication) or pneumatic dilation, and comparing variations of the peroral endoscopic myotomy procedure (North, 2024; Sobral, 2024; Zhang, 2023). In adults with or without previous endoscopic or surgical treatment, peroral endoscopic myotomy is effective in achieving durable achalasia remission.

Compared to Heller myotomy with fundoplication, complication rates are similar. The most commonly reported severe complications were perforations or esophageal leakage requiring surgical intervention, sepsis, mediastinitis, and acute respiratory distress syndrome, and their incidences were rare. Peroral endoscopic myotomy is reportedly associated with a higher incidence of gastroesophageal reflux in some observational studies, but meta-analyses found no statistically significant differences between the procedures. Generally, gastroesophageal reflux can be successfully managed medically over time.

A systematic review and meta-analysis of 20 observational studies included 1,394 participants who underwent peroral endoscopic myotomy and 3,745 who underwent laparoscopic Heller myotomy with fundoplication. Peroral endoscopic myotomy was associated with significantly shorter operative time and length of stay, less postoperative pain, and comparable or higher clinical success during the initial months, depending on how clinical success was defined. There were no statistically significant differences between surgical techniques with respect to surgical complications, post-operative complications, re-intervention rates, gastroesophageal reflux rates, or health-related quality of life. Participants who underwent peroral endoscopic myotomy experienced a significantly lower length of stay (2.1 days versus 2.7 days, $P = .0001$; 14 studies) and less post-surgical pain in terms of lower analgesic medication use (1.6 days versus 2.3 days, $P = .03$; two studies) (Sobral, 2024).

A systematic review of 31 studies noted that, in large cohort studies, peroral endoscopic myotomy compared favorably to pneumatic dilation. Peroral endoscopic myotomy resulted in long-lasting symptomatic improvement without the need for additional intervention or without an increase in adverse events, particularly in patients with type III achalasia. Randomized studies demonstrated peroral endoscopic myotomy and laparoscopic Heller myotomy had similar safety and efficacy profiles of up to 24 months after the procedures. The comparative rates of gastroesophageal reflux across the three procedures was mixed. Pneumatic dilation appears to have the shortest length of stay, while laparoscopic Heller myotomy had the longest, but the results varied across individual studies (North, 2024).

In 21 studies ($n = 2,698$) that reviewed long-term outcomes of peroral endoscopic myotomy for achalasia, clinical success rates after two, three, four, and five years were 91.3%, 90.4%, 89.8%, and 82.2%. The pooled long-term clinical success rates for type I, II, and III achalasia were 86.1%, 87.9%, and 83.9%, respectively. The pooled incidences of symptomatic reflux and reflux esophagitis were 23.9% and 16.7%, respectively (Zhang, 2023).

As a salvage procedure, peroral endoscopic myotomy can be successfully performed after previous endoscopic or surgical treatment and achieve high rates of clinical success (defined as post- peroral endoscopic myotomy Eckardt score ≤ 3). The pooled rates of postoperative symptomatic reflux, esophagitis, and abnormal pH monitoring were 36.9%, 33.0%, and 47.8%, respectively (Huang, 2021). The efficacy of peroral endoscopic myotomy in patients who had undergone prior intervention was comparable to that of the treatment-naïve, in terms of high pooled technical (98.0%) and clinical (90.8%) success rates and in significantly reduced Eckardt scores and lower esophageal sphincter pressures (Tan, 2021).

In children with idiopathic achalasia, limited evidence suggests peroral endoscopic myotomy is feasible and safe, and may be efficacious in decreasing Eckardt symptom scores with some durability. A systematic review and meta-analysis of 14 studies comprised 419 children with type I (30.6%), type II (63.8%), and type III (5.6%) achalasia. The pooled rate of technical success was 97.1%. The pooled clinical success rate (Eckardt ≤ 3) was

88% based on intention-to-treat analysis. After peroral endoscopic myotomy, the pooled mean reduction in Eckardt scores was 6.71 ($P < .001$). The overall adverse event rate was 12.9%, and the rates of major adverse events and erosive esophagitis were 4.2% and 26.3%, respectively (Nabi, 2022).

Gastroparesis

The evidence for gastric peroral endoscopic myotomy from systematic reviews and meta-analyses consists of observational studies of moderate-to-high quality (Aziz, 2023; Malik, 2024; Stojilkovic, 2023). Studies enrolled adult patients with refractory gastroparesis following intrapyloric botulinum toxin injection and, to a lesser extent, gastric stimulators, surgical pyloroplasty, percutaneous endoscopic gastro-jejunal tube insertion, and transpyloric stenting. The most prevalent etiologies of gastroparesis were prior foregut surgery, idiopathic causes, and diabetes. The most commonly used measure of clinical success was change in the Gastroparesis Cardinal Symptom Index; a minimum 1-point decrease or a 25%-50% improvement in symptoms from baseline was generally considered clinically significant.

The procedure appears safe and effective for the treatment of patients with refractory gastroparesis regardless of etiology or prior intervention. Diabetic patients with gastroparesis exhibited the most substantial improvement in the Gastroparesis Cardinal Symptom Index score, and the highest overall clinical success was noted in individuals who acquired gastroparesis following surgery (Malik, 2024). Other outcomes such as gastric emptying and Endoscopic Functional Luminal Imaging Probe measurements were reported inconsistently, but generally showed short-term post-procedural improvement. Reported adverse events included capnoperitoneum, bleeding, perforations, and abdominal pain, of varying severities (Malik, 2024; Stojilkovic, 2023).

Stojilkovic (2023) examined the long-term effectiveness of gastric peroral endoscopic myotomy in 11 studies ($n = 900$). Using an average decrease of one point in the Gastroparesis Cardinal Symptom Index score from baseline as the measure of clinical success, 92.8% (662/713) achieved clinical success at one-year follow-up, 91.5% (421/460) at two-year follow-up, 100% (270/270) at three-year follow-up, and 100% (102/102) at four-year follow-up. Adverse events occurred in 7.4% (62/835 patients in nine studies), none leading to deaths.

Evidence supporting a clear advantage over surgical pyloroplasty is inconclusive. Indirect comparisons suggest gastric peroral endoscopic (versus surgical procedures pyloromyotomy and pyloroplasty) had a shorter procedural time ($P < .001$) and shorter length of stay ($P < .001$). Reduction in symptoms score did not differ between groups (Aziz, 2023).

Esophageal diverticula

A systematic review and meta-analysis (Mandavdhare, 2021) of 19 studies ($n = 341$ patients) compared the efficacy and safety of peroral endoscopic myotomy to flexible endoscopic septum division for esophageal diverticula. The clinical success, technical success, and adverse event rates for peroral endoscopic myotomy were 87%, 95.19%, and 10.22%, respectively. Compared to flexible endoscopic septum division, peroral endoscopic myotomy was associated with higher clinical success (relative risk 1.13, 95% confidence interval 1.05 to 1.22, $n =$ eight studies) and comparable technical success (relative risk 0.99, 95 confidence interval 0.95 to 1.02, $n =$ eight studies). The procedure time, length of hospital stay, and recurrence rate were comparable between procedures.

In 2016, no policy changes are warranted at this time.

In 2017, we added no new findings, and no policy changes are warranted at this time.

In 2018, no policy changes are warranted at this time. The policy ID was changed from CP# 08.03.04 to CCP.1199.

In 2019, we updated the references.

In 2020, we changed the coverage for peroral endoscopic myotomy from investigational to medically necessary for treatment-naïve patients.

In 2021, we added new evidence addressing peroral endoscopic myotomy in pediatric populations, as a salvage procedure for esophageal achalasia in adults, and for esophageal diverticula. We added peroral endoscopic myotomy as a salvage procedure as a new medically necessary indication for adults with esophageal achalasia.

In 2022, we updated the references.

In 2023, we updated the references.

In 2024, we reorganized the findings section, updated the references, and added new guidelines that support expanding medical necessity criteria to children with esophageal achalasia and adults with medically refractory gastroparesis.

References

On September 11, 2024, we searched PubMed and the databases of the Cochrane Library, the U.K. National Health Services Centre for Reviews and Dissemination, the Agency for Healthcare Research and Quality, and the Centers for Medicare & Medicaid Services. Search terms were “peroral endoscopic myotomy,” “gastroparesis,” and “esophageal achalasia” (MeSH). We included the best available evidence according to established evidence hierarchies (typically systematic reviews, meta-analyses, and full economic analyses, where available) and professional guidelines based on such evidence and clinical expertise.

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Policy updates

10/2015: initial review date and clinical policy effective date: 1/2016

10/2016: Policy references updated.

10/2017: Policy references updated.

10/2018: Policy references updated. Policy ID changed.

11/2019: Policy references updated. Gastric peroral endoscopic myotomy added.

11/2020: Policy references updated. Coverage changed to medically necessary.

11/2021: Policy references updated. Coverage modified.

11/2022: Policy references updated.

11/2023: Policy references updated.

11/2024: Policy references updated. Coverage modified.