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#### **Peroral Endoscopic Myotomy Policy**

##### **Indication/Usage:**

Achalasia is a primary esophageal motility disorder which is characterized by impaired relaxation of lower esophageal sphincter. These motor abnormalities result in impaired food bolus transit in the esophagus, which causes symptoms such as dysphagia, regurgitation, chest pain and weight loss. The chest pain experienced, also known as cardiospasm and non-cardiac chest pain can often be mistaken for a heart attack. It can be extremely painful in some patients. Achalasia tends to become progressively worse over time and to involve both fluids and solids and nutrients are not being absorbed

##### **Achalasia subtypes:**

- Type I: (classic achalasia): Swallowing results in no significant change in esophageal pressurization.
- Type II: Swallowing results in simultaneous pressurization that spans the entire length of the esophagus.
- Type III: (spastic achalasia): Swallowing results in abnormal, lumen-obliterating contractions or spasms.

## **Medical Indications for Authorization Commercial Members**

Peroral endoscopic myotomy (POEM) is considered medically necessary when **ALL** of the following criteria have been met:

- Diagnosis of primary achalasia confirmed by esophageal manometry
- Active symptoms due to type III achalasia (Dysphagia, Regurgitation, Chest pain, Weight Loss)
- POEM is being proposed as an alternative to pneumatic dilation or myotomy (open or laparoscopic procedures)

Gastric peroral endoscopic myotomy (G-POEM) is considered medically necessary when **ALL** of the following criteria have been met:

- Confirmed diagnosis of severe gastroparesis
- Absence of mechanical obstruction confirmed by Esophagogastroduodenoscopy (EGD)
- Gastric emptying scan (GES) has confirmed delayed gastric emptying with gastric retention greater than 20% at four hours
- Failure of conservative management for greater than 6 months, including use of any of the following, either alone or in combination: dietary modification, prokinetics and antiemetics.

## **Medicare Members**

### **CMS LCD ID L38747 Peroral Endoscopic Myotomy (POEM) Palmetto**

Coverage Guidance

#### **Coverage Indications, Limitations, and/or Medical Necessity**

Achalasia is a disorder of the esophagus that makes it difficult for food and liquid to pass into the stomach. Achalasia results from the degeneration of ganglion cells in the myenteric plexus in the wall of the esophagus. This degeneration leads to failure of relaxation of the lower esophageal sphincter (LES) together with loss of peristalsis in the distal esophagus. The most common symptoms in patients with achalasia are dysphagia for solids and liquids as well as regurgitation of undigested foods or saliva. Additional symptoms include chest pain, heartburn, and difficulty belching. Complications of achalasia may include progressive dilation of the

esophagus (megaesophagus) possibly leading to esophagectomy. Patients with achalasia also at increased risk of developing esophageal cancer. Achalasia can be treated with pneumatic dilatation (PD), botulinum toxin injection, and surgical myotomy. Laparoscopic Heller Myotomy (LHM) is the most common surgical myotomy procedure for treatment of achalasia.

PERORAL ENDOSCOPIC MYOTOMY (POEM) is the endoscopic complement of surgical myotomy and is a newer, less invasive procedure for the management of achalasia. POEM is an endoscopic procedure, which creates a tunnel in the submucosal layer of the esophagus and proximal stomach. Through this submucosal tunnel, an esophageal and gastric myotomy are made using a flexible endoscope.<sup>1</sup> The POEM procedure is performed in 4 steps: 1) mucosal incision/entry into the submucosa, 2) creation of a submucosal tunnel, 3) myotomy, and 4) closure of the mucosal incision.<sup>6,7,8,12,21,23,24,31</sup>

POEM is a form of natural orifice transluminal endoscopic surgery (NOTES). The procedure is performed perorally, without any incisions in the chest or abdomen. The advantage of this approach is to reduce procedure-related pain and return patients to regular activities sooner than surgeries requiring external incisions.

POEM may be considered medically necessary for treatment of symptomatic, manometrically proven primary idiopathic achalasia, types I, II, or III. Prior to performing a POEM procedure, it is crucial to confirm that patients have the correct diagnosis of achalasia, and the following documentation must be included in the clinician's preoperative evaluation:

1. **History and physical exam** – including a standardized, validated symptom assessment form completed by all patients (i.e., Eckardt score  $\geq 3$ );
2. **High-resolution esophageal manometry (HRM)** – achalasia is subclassified according to the Chicago Classification of esophageal motility disorders, which is based upon the result of a high-resolution esophageal manometry test;
3. **Contrast esophagram** – findings on contrast esophagram that are suggestive of achalasia include a narrowed esophagogastric junction (EGJ) with a "bird-beak" appearance and esophageal aperistalsis. Late or end-stage achalasia may give the appearance that the esophagus is significantly dilated, angulated, and tortuous, giving it a sigmoid shape<sup>35</sup>;
4. **Esophagogastroduodenoscopy (EGD)** – EGD sometimes reveals a dilated esophagus that contains residual material with normal appearing esophageal mucosa.

**Contraindications** — if 1 of the following conditions is present, the patient should not undergo POEM:

5. Severe erosive esophagitis
6. Significant coagulation disorders
7. Liver cirrhosis with portal hypertension
8. Severe pulmonary disease
9. Esophageal malignancy

10. Prior therapy that may compromise the integrity of esophageal mucosa or lead to submucosal fibrosis, including recent esophageal surgery, radiation, endoscopic mucosal resection, or radiofrequency ablation

Previous therapies for achalasia, such as PD, botulinum toxin injection, or LHM, are **not** contraindications to POEM.

Prior to treatment with POEM, patients should be educated on the risk of gastroesophageal reflux disease (GERD). Also, follow-up acid suppression treatment should be considered after POEM. Patients should be counseled to ensure that treatments exist with a lower incidence of post procedure GERD, such as LHM and PD.

POEM is considered a safe but complex procedure. POEM will be considered medically reasonable and necessary only if it is performed by adequately trained, experienced physicians in high-volume centers. These centers must have the available staff to address any potential adverse events from POEM immediately, including but not limited to gastrointestinal or cardiothoracic complications.

### **CPT Codes**

**43497** Lower esophageal myotomy, transoral (ie, peroral endoscopic myotomy [POEM])  
**43999** Unlisted procedure, stomach (G-POEM)

### **Limitations**

SummaCare considers the POEM and G-POEM for any indications not listed above experimental, investigational, or unproven because the effectiveness of these approaches has not been established

### **Coverage Decisions**

Coverage decisions made per CMS Guidelines, Hayes Research and industry standards research

### **Plans Covered By This Policy**

Commercial and Medicare

**Self-funded Commercial groups refer to plan document for coverage**

### **Sources Reviewed**

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