

FEP 2.01.91 Peroral Endoscopic Myotomy for Treatment of Esophageal Achalasia

Effective Date: April 15, 2018

Related Policies:

2.01.38 Transesophageal Endoscopic Therapies for Gastroesophageal Reflux Disease
7.01.137 Magnetic Esophageal Ring to Treat Gastroesophageal Reflux Disease

Peroral Endoscopic Myotomy for Treatment of Esophageal Achalasia

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. This procedure is intended to reduce the total number of incisions needed and thus the overall invasiveness of surgery.

FDA 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.

POLICY STATEMENT

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

BENEFIT APPLICATION

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

RATIONALE

Summary of Evidence

For individuals who have achalasia who receive POEM, the evidence includes systematic reviews, nonrandomized comparative studies, and case series. Relevant outcomes are symptoms, functional outcomes, health status measures, resource utilization, and treatment-related morbidity. The comparative studies have primarily reported similar outcomes with POEM and with Heller myotomy for symptom relief, as assessed by the Eckardt score. Some studies have shown 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.

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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 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.

SUPPLEMENTAL INFORMATION

Practice Guidelines and Position Statements

American Society of Gastrointestinal and Endoscopic Surgeons

In 2014, the American Society of Gastrointestinal and Endoscopic Surgeons issued evidence-based, consensus guidelines on the use of endoscopy in the evaluation and management of dysphagia, including esophageal achalasia.²⁸ The Society recommended that:

“... Endoscopic and surgical treatment options for achalasia should be discussed with the patient. In patients who opt for endoscopic management and are good surgical candidates, pneumatic dilation with large-caliber balloon dilators for the endoscopic treatment of achalasia was recommended... Long-term data and randomized trials comparing peroral endoscopic myotomy to conventional modalities of management are necessary before it can be adopted into clinical practice, but the procedure is becoming more widely used in expert centers.”

American College of Gastroenterology

In 2013, the American College of Gastroenterology issued clinical guidelines on the diagnosis and management of achalasia.²⁹ Peroral endoscopic myotomy was discussed as an emerging therapy and stated to have promise as an alternative to the laparoscopic approach. The guidelines further stated that randomized prospective comparison trials are needed, and the procedure should be performed in the context of clinical trials.

Society of American Gastrointestinal and Endoscopic Surgeons

In 2012, the Society of American Gastrointestinal and Endoscopic Surgeons issued evidence-based, consensus guidelines on the surgical management of esophageal achalasia. The guidelines stated that the peroral endoscopic myotomy technique “is in its infancy and further experience is needed before providing recommendations.”³⁰

U.S. Preventive Services Task Force Recommendations

Not applicable.

Medicare National Coverage

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

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POLICY HISTORY

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

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