Peroral Endoscopic Myotomy for Treatment of Esophageal Achalasia and Gastroparesis

Medicare Advantage Medical Policy #MA-010
Original Effective Date: 03/01/2024
Current Effective Date: 08/01/2025

Applies to all products administered or underwritten by the Health Plan, unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

When Services May Be Eligible for Coverage

Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:

- *Benefits are available in the member's contract/certificate, and*
- *Medical necessity criteria and guidelines are met.*

Based on review of available data, the Health Plan may consider peroral endoscopic myotomy (POEM) as a treatment for esophageal achalasia to be **eligible for coverage.****

Patient Selection Criteria

Coverage eligibility may be considered for peroral endoscopic myotomy (POEM) as a treatment for esophageal achalasia to be medically appropriate when **ALL** of the following criteria are met:

- The individual is 18 years or older; **AND**
- Has an established diagnosis of primary achalasia (I, II or III) based on esophageal manometry; **AND**
- Eckardt symptom score is greater than 3 (see Policy Guideline section); **AND**
- There is no history of esophageal malignancy or premalignant esophageal lesion, radiation therapy, radiofrequency ablation, previous esophageal surgery for achalasia, myotomy or previous open surgery of the stomach or esophagus.

When Services Are Considered Investigational

Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

Based on review of available data, the Health Plan considers peroral endoscopic myotomy (POEM) when the coverage criteria are not met and for all other indications to be **investigational.***

Based on review of available data, the Health Plan considers gastric peroral endoscopic myotomy as a treatment for gastroparesis to be **investigational.***

Policy Guidelines

The three types of achalasia defined by the Chicago Classification include:

- Type I – Classic Achalasia – incomplete lower esophageal sphincter (LES) relaxation, aperistalsis and absence of esophageal pressurization with 100% failed peristalsis and a distal contractile integral (DCI) < 100mgHg.
- Type II – Incomplete LES relaxation, aperistalsis and panesophageal pressurization in at least 20% of swallows.
- Type III – (Spastic Achalasia) – Incomplete LES relaxation and premature contractions in at least 20% of swallows.

Eckardt symptom score is based on a 4-item self-report scale measuring weight loss in kilograms (kg), chest pain, regurgitation, and dysphagia. Each item is graded 0 to 3, with a maximum score of 12. Scores greater than or equal to 3 are considered suggestive of active achalasia:

Score	Dysphagia	Regurgitation	Retrosternal pain	Weight loss (kg)
0	None	None	None	None
1	Occasional	Occasional	Occasional	<5
2	Daily	Daily	Daily	5-10
3	Each meal	Each meal	Each meal	>10

Background/Overview

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. Achalasia is estimated to affect 18 out of every 100,000 individuals in the U.S., and the incidence of 10.5 per 100,000 person-years, with increased rates reported with more advanced age.

Treatment

Treatment options for achalasia have included pharmacotherapy (eg, injections with botulinum toxin), pneumatic dilation, and laparoscopic Heller myotomy. Although the latter 2 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 subsequent intervention of 0.6% have been reported.

Peroral endoscopic myotomy (POEM) is a novel endoscopic procedure developed in Japan. This procedure 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 (LES) 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 LES muscle layers. Cutting the dysfunctional muscle fibers that prevent the LES from opening allows food to enter the stomach more easily.

Note that the acronym POEM in this review refers to *peroral endoscopic myotomy*. POEMS syndrome, which has a similar acronym, is discussed in in medical policy 00060 Hematopoietic Cell Transplantation for Plasma Cell Dyscrasias, Including Multiple Myeloma and POEMS Syndrome.

Gastroparesis
Gastroparesis is characterized by symptoms of nausea, vomiting, bloating, early satiety, and pain, which is caused by delayed gastric emptying without mechanical obstruction. The estimated U.S. prevalence of difficult to ascertain due to the weak correlation of symptoms with gastric emptying which results in a high rate of underdiagnosis. A systematic review of the literature determined that the prevalence of confirmed gastroparesis, characterized by symptoms and delayed gastric emptying, varies widely in the general population, with estimates ranging from 14 to 268 cases per 100,000 adults. Furthermore, the incidence of this condition spans from 1.9 to 6.3 per 100,000 person-years.

Treatment
Treatment options for gastroparesis have included dietary modification (smaller meal sizes, avoidance of carbonated beverages, smoking or high doses of alcohol, and in some cases enteral nutrition via jejunostomy), optimization of hydration and glycemic control, pharmacotherapy (eg, antiemetics or Metoclopramide, or off-label medications for symptom control such as domperidone, erythromycin, tegaserod or centrally acting antidepressants), gastric electrical stimulation, venting gastrostomy, feeding jejunostomy, intra-pyloric botulinum injection, partial gastrectomy, and pyloroplasty. Gastric peroral endoscopic myotomy (G-POEM), which endoscopically performs the equivalent of pyloroplasty, is being investigated for the treatment of gastroparesis.
The G-POEM procedure involves tunneling an endoscope down the esophagus toward the esophageal-gastric junction. A surgeon performs the myotomy by cutting the pylorus muscles through a submucosal tunnel created in the proximal esophageal mucosa.

Symptom relief may be measured by the Gastroparesis Cardinal Symptom Index (GCSI), which is comprised of 3 major symptoms of gastroparesis: postprandial fullness/early satiety (4 items), nausea/vomiting (3 items), and bloating (2 items). Each item receives a score from 0 (none) to 5 (severe), for a maximum score of 45. An average GCSI score of ≥ 3 is defined as severe gastroparesis. Treatment-related morbidity of concern is infection, ulcers near the pylorus, bleeding or tears in the gastric mucosa Symptom relief may be experienced shortly following the procedure. Assessment of durability of relief requires a follow-up of months to years.

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)
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/Source

This medical policy was developed through consideration of peer-reviewed medical literature generally recognized by the relevant medical community, U.S. Food and Drug Administration approval status, nationally accepted standards of medical practice and accepted standards of medical practice in this community, technology evaluation centers, reference to federal regulations, other plan medical policies, and accredited national guidelines.

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.

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.

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, 2 RCTs, and several nonrandomized studies. All studies included in these reviews were observational. 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 61 % at 1 year to 75% at 3 years in the meta-analyses. One RCT demonstrated a notably higher success rate and improvement in gastric retention for G-POEM compared to a sham control group, with the most significant benefit observed in patients with diabetic gastroparesis. Another RCT indicated a trend towards superior 3-month clinical outcomes for POEM over botulinum toxin injection, although the 1-year clinical success rate on intention-to-treat analysis was not significantly higher. Study limitations include small number of participants, insufficient follow-up to define long-term effects, and results may not be generalizable to the general population (performed by experienced endoscopist). The evidence is insufficient to determine that the technology results in an improvement in the net health outcome. Large, controlled trials with longer follow-up are needed to identify the individuals most suited for the procedure.

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. 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 (AGA) Institute published a clinical practice update on the use of POEM for the treatment of achalasia. 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 AGA Institute issued a clinical practice update commentary regarding gastric peroral endoscopic myotomy for gastroparesis. 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 undergo 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
    - 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:
    - Patients with opioid dependence should be weaned off opioids whenever possible and have their gastric emptying re-evaluated.
    - 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 Endoscopy
In 2020, the American Society of Gastrointestinal Endoscopy (ASGE) issued an evidence-based guideline on the management of achalasia. 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. 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.

In 2021, SAGES issued its own evidence-based guidelines for the use of POEM for the treatment of achalasia. 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.

Ongoing and Unpublished Clinical Trials
Some currently ongoing and unpublished trials that might influence this review are listed in Table 2.

Table 2. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
Ongoing			
NCT01793922	A Prospective Randomized Multi-center Study Comparing Endoscopic Pneumodilation and Per Oral Endoscopic Myotomy (POEM) as Treatment of Idiopathic Achalasia	150	Jan 2025
NCT04434781	Gastric Per-Oral Endoscopic Myotomy (G-POEM) for the Treatment of Gastroparesis: A Database Repository	75	Aug 2024
NCT05830994	Randomized Sham-controlled Trial Investigating Efficacy of Gastric Peroral Endoscopic Myotomy in Treatment of Diabetic Gastroparesis	20	Jun 2025
NCT04869670	A Pilot and Feasibility Trial of G-POEM for Gastroparesis to Assess Safety, Physiological Mechanisms and Efficacy	30	Jun 2025
NCT02518542	Per Oral Endoscopic Myotomy (POEM) and Prolonged Dilatation (PRD) as Additional Endoscopic Treatment Options for Achalasia and Other Esophageal Motility Disorders	400	Jun 2027
Unpublished			
NCT01601678	Endoscopic Versus Laparoscopic Myotomy for Treatment of Idiopathic Achalasia: A Randomized, Controlled Trial	240	May 2023 (last update posted June 2023)

NCT No.	Trial Name	Planned Enrollment	Completion Date
NCT01832779	Prospective Evaluation of the Clinical Utility of Peroral Endoscopic Myotomy (POEM)	143	May 2024 (last update posted May 2024)
NCT03228758	Efficacy of Anterior Versus Posterior Myotomy Approach in Peroral Endoscopic Myotomy (POEM) for the Treatment of Achalasia - a Single Operator Analysis	89	May 2019 (last update posted May 2020)

NCT: national clinical trial.

References

1. Werner YB, Hakanson B, Martinek J, et al. Endoscopic or surgical myotomy in patients with idiopathic achalasia. N Engl J Med. 2019; 381(23):2219-2229.
2. Gaber CE, Eluri S, Cotton CC, et al. Epidemiologic and Economic Burden of Achalasia in the United States. Clin Gastroenterol Hepatol. Feb 2022; 20(2): 342-352.e5. PMID 33652152
3. Cheatham JG, Wong RK. Current approach to the treatment of achalasia. Curr Gastroenterol Rep. Jun 2011; 13(3): 219-25. PMID 21424734
4. Pandolfino JE, Kahrilas PJ. Presentation, diagnosis, and management of achalasia. Clin Gastroenterol Hepatol. Aug 2013; 11(8): 887-97. PMID 23395699
5. 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
6. Inoue H, Minami H, Kobayashi Y, et al. Peroral endoscopic myotomy (POEM) for esophageal achalasia. Endoscopy. Apr 2010; 42(4): 265-71. PMID 20354937
7. 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
8. 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/
9. Dilmaghani S, Zheng T, Camilleri M. Epidemiology and Healthcare Utilization in Patients With Gastroparesis: A Systematic Review. Clin Gastroenterol Hepatol. Aug 2023; 21(9): 2239-2251.e2. PMID 35870768
10. Eckardt AJ, Eckardt VF. Treatment and surveillance strategies in achalasia: an update. Nat Rev Gastroenterol Hepatol. Jun 2011; 8(6): 311-9. PMID 21522116
11. 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

12. 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
13. Akintoye E, Kumar N, Obaitan I, et al. Peroral endoscopic myotomy: a meta-analysis. Endoscopy. Dec 2016; 48(12): 1059-1068. PMID 27617421
14. 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
15. 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
16. 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
17. 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
18. 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
19. Aiolfi A, Bona D, Riva CG, et al. Systematic Review and Bayesian Network Meta-Analysis Comparing Laparoscopic Heller Myotomy, Pneumatic Dilatation, and Peroral Endoscopic Myotomy for Esophageal Achalasia. J Laparoendosc Adv Surg Tech A. Feb 2020; 30(2): 147-155. PMID 31364910
20. 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
21. 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
22. 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): 1098-103. PMID 24169175
23. 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
24. 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
25. 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

26. 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
27. 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
28. 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
29. 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
30. 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
31. 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
32. 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
33. 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
34. 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
35. 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
36. 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
37. 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
38. 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
39. 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
40. Miller HJ, Neupane R, Fayezizadeh 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

41. 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
42. 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
43. Wang X, Tan Y, Lv L, et al. Peroral endoscopic myotomy versus pneumatic dilation for achalasia in patients aged ≥ 65 years. Rev Esp Enferm Dig. Oct 2016; 108(10): 637-641. PMID 27649684
44. 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
45. 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
46. 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
47. 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
48. 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
49. Boeckxstaens 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
50. 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
51. 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
52. 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
53. 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
54. 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
55. 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
56. 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
57. 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
58. 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
59. 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
60. 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
61. 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
62. 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
63. 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
64. Petrosyan M, Mostammand 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
65. 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
66. 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
67. 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
68. 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
69. 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.

70. 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
71. Hernández Mondragón 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
72. 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
73. 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
74. 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
75. 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
76. Husťak R, Vacková Z, Krajciova 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
77. 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
78. 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
79. 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
80. 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
81. 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
82. 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

83. 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
84. 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
85. Gonzalez JM, Mion F, Pioche M, et al. Gastric peroral endoscopic myotomy versus botulinum toxin injection for the treatment of refractory gastroparesis: results of a double-blind randomized controlled study. Endoscopy. May 2024; 56(5): 345-352. PMID 38141620
86. 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
87. 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
88. Khashab MA, Wang AY, Cai Q. AGA Clinical Practice Update on Gastric Peroral Endoscopic Myotomy for Gastroparesis: Commentary. Gastroenterology. Jun 2023; 164(7): 1329-1335.e1. PMID 37086247
89. 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
90. Zaninotto G, Bennett C, Boeckxstaens G, et al. The 2018 ISDE achalasia guidelines. Dis Esophagus. Sep 01 2018; 31(9). PMID 30169645
91. 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

Original Effective Date: 03/01/2024
Current Effective Date: 08/01/2025

03/01/2024	New policy.
08/22/2024	Utilization Management Committee review/approval. Coverage eligibility unchanged.
05/20/2025	Utilization Management Committee review/approval. Added investigational statement for gastric peroral endoscopy myotomy as a treatment for gastroparesis. Added code 43999.

Next Scheduled Review Date: 05/2026

Coding

The five character codes included in the Health Plan Medical Policy Coverage Guidelines are obtained from Current Procedural Terminology (CPT®)‡, copyright 2025 by the American Medical Association (AMA). CPT is developed by the AMA as a listing of descriptive terms and five character

identifying codes and modifiers for reporting medical services and procedures performed by physician.

The responsibility for the content of the Health Plan Medical Policy Coverage Guidelines is with the Health Plan and no endorsement by the AMA is intended or should be implied. The AMA disclaims responsibility for any consequences or liability attributable or related to any use, nonuse or interpretation of information contained in the Health Plan Medical Policy Coverage Guidelines. Fee schedules, relative value units, conversion factors and/or related components are not assigned by the AMA, are not part of CPT, and the AMA is not recommending their use. The AMA does not directly or indirectly practice medicine or dispense medical services. The AMA assumes no liability for data contained or not contained herein. Any use of CPT outside of the Health Plan Medical Policy Coverage Guidelines should refer to the most current Current Procedural Terminology which contains the complete and most current listing of CPT codes and descriptive terms. Applicable FARS/DFARS apply.

CPT is a registered trademark of the American Medical Association.

Codes used to identify services associated with this policy may include (but may not be limited to) the following:

Code Type	Code
CPT	43497, 43499, 43999
HCPCS	No codes
ICD-10 Diagnosis	All related diagnoses

*Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or
B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:
    1. Consultation with technology evaluation center(s);
    2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
    3. Reference to federal regulations.

**Medically Necessary (or "Medical Necessity") - Health care services, treatment, procedures, equipment, drugs, devices, items or supplies that a Provider, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are:

A. In accordance with nationally accepted standards of medical practice;
B. Clinically appropriate, in terms of type, frequency, extent, level of care, site and duration, and considered effective for the patient's illness, injury or disease; and
C. Not primarily for the personal comfort or convenience of the patient, physician or other health care provider, and not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.

For these purposes, "nationally accepted standards of medical practice" means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, Physician Specialty Society recommendations and the views of Physicians practicing in relevant clinical areas and any other relevant factors.

‡ Indicated trademarks are the registered trademarks of their respective owners.

NOTICE: If the Patient's health insurance contract contains language that differs from the Health Plan's Medical Policy definition noted above, the definition in the health insurance contract will be relied upon for specific coverage determinations.

NOTICE: Medical Policies are scientific based opinions, provided solely for coverage and informational purposes. Medical Policies should not be construed to suggest that the Health Plan recommends, advocates, requires, encourages, or discourages any particular treatment, procedure, or service, or any particular course of treatment, procedure, or service.

NOTICE: Federal and State law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over Medical Policy and must be considered first in determining eligibility for coverage.

Medicare Advantage Members
Established coverage criteria for Medicare Advantage members can be found in Medicare coverage guidelines in statutes, regulations, National Coverage Determinations (NCD)s, and Local Coverage Determinations (LCD)s. To determine if a National or Local Coverage Determination addresses coverage for a specific service, refer to the Medicare Coverage Database at the following link: https://www.cms.gov/medicare-coverage-database/search.aspx. You may wish to review the Guide to the MCD Search here: https://www.cms.gov/medicare-coverage-database/help/mcd-benehelp.aspx.

When coverage criteria are not fully established in applicable Medicare statutes, regulations, NCDs or LCDs, internal coverage criteria may be developed. This policy is to serve as the summary of evidence, a list of resources and an explanation of the rationale that supports the adoption of this internal coverage criteria.

InterQual®
Interqual® is utilized as a source of medical evidence to support medical necessity and level of care decisions. InterQual® criteria are intended to be used in connection with the independent professional medical judgment of a qualified health care provider. InterQual® criteria are clinically based on best practice, clinical data, and medical literature. The criteria are updated continually and released annually. InterQual® criteria are a first-level screening tool to assist in determining if the proposed services are clinically indicated and provided in the appropriate level or whether further evaluation is required. The utilization review staff does the first-level screening. If the criteria are met, the case is approved; if the criteria are not met, the case is referred to the medical director.