Molina Clinical Policy
Gastric Electrical Stimulation
Policy No. 414

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DISCLAIMER

This Molina Clinical Policy (MCP) is intended to facilitate the Utilization Management process. Policies are not a supplementation or recommendation for treatment; Providers are solely responsible for the diagnosis, treatment, and clinical recommendations for the Member. It expresses Molina's determination as to whether certain services or supplies are medically necessary, experimental, investigational, or cosmetic for purposes of determining appropriateness of payment. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered (e.g., will be paid for by Molina) for a particular Member. The Member's benefit plan determines coverage – each benefit plan defines which services are covered, which are excluded, and which are subject to dollar caps or other limits. Members and their Providers will need to consult the Member's benefit plan to determine if there are any exclusion(s) or other benefit limitations applicable to this service or supply. If there is a discrepancy between this policy and a Member's plan of benefits, the benefits plan will govern. In addition, coverage may be mandated by applicable legal requirements of a State, the Federal government or CMS for Medicare and Medicaid Members. CMS's Coverage Database can be found on the CMS website. The coverage directive(s) and criteria from an existing National Coverage Determination (NCD) or Local Coverage Determination (LCD) will supersede the contents of this MCP and provide the directive for all Medicare members. References included were accurate at the time of policy approval and publication.

OVERVIEW

Gastroparesis, or delayed gastric emptying, is a disorder in which the stomach fails to empty its contents at a normal rate. This condition can cause symptoms such as bloating, abdominal discomfort, nausea, vomiting, and early satiety. In severe cases, complications can lead to weight loss, dehydration, electrolyte imbalances, and malnutrition. Initial management typically involves conservative approaches such as dietary modification, pharmacologic therapy, and optimization of glycemic control in patients with diabetes. Supportive interventions, including intravenous hydration or nutritional supplementation, may also be required. When symptoms persist despite these measures, the condition is considered refractory (Hasler 2023).

Gastric electrical stimulation (GES) is a treatment option for refractory gastroparesis. The therapy involves implanting electrodes into the gastric wall, usually along the greater curvature of the stomach. These electrodes are connected to a small, battery-powered pulse generator, which is implanted in a subcutaneous pocket in the abdominal wall. The device is programmed externally to optimize therapy for each patient. The procedure is most commonly performed laparoscopically, although an open approach may be used if necessary. Once activated, the generator delivers electrical pulses to the stomach wall (Shanker et al. 2021; Hasler 2023).

The precise mechanism of action of GES remains unclear. Initially, it was thought that electrical impulses may improve the rate of gastric emptying; however, this has not been consistently demonstrated. Symptom improvement may instead result from neuromodulation, in which stimulation of the vagal afferent pathways influence central nausea and vomiting centers. Some studies also suggest that GES may enhance gastric accommodation, which could contribute to symptom relief (Shanker et al. 2021; Hasler 2023).

Regulatory Status

The Enterra™ Therapy System (Medtronic, Inc.), received U.S. Food and Drug Administration (FDA) in 2000 under a Humanitarian Device Exemption for the treatment of chronic, intractable nausea and vomiting secondary to diabetic or idiopathic gastroparesis (FDA 2000). Temporary GES, in which endoscopically placed cardiac pacing leads are connected to an external stimulator, has also been studied as a less invasive method to assess response prior to permanent implantation. This is an off-label use, as the only FDA-approved configuration requires intramuscular placement of pacing leads within the gastric antrum.

On October 20, 2023, the Enterra II® System received FDA supplemental approval for Magnetic Resonance (MR) Conditional use. This designation permits patients with the Enterra II System to undergo Magnetic Resonance Imaging (MRI) examinations of the head and upper or lower extremities under specified conditions.

GES has also been investigated as a potential therapy for patients with obesity. In this context, stimulation is intended to induce cause early satiety and reduce appetite, leading to weight loss. However, the mechanisms underlying these effects are not well understood, and no GES devices are currently approved by the FDA for the treatment of obesity.

COVERAGE POLICY

Gastric electrical stimulation for the treatment of refractory gastroparesis may be **considered medically necessary** when ALL the following criteria are met:

1. Member is age 18 or older

2. Diagnosis of gastroparesis with diabetic or idiopathic etiology

3. Delayed gastric emptying, defined by > 60% retention at two hours or > 10% retention at four hours, as measured by standardized gastric emptying study (e.g., scintigraphy). (**Note:** Member must be free of any medication that can cause gastroparesis (e.g., glucagon-like peptide-1 (GLP-1) medications, opioids, etc.) for at least 2 months prior to the study unless clinically infeasible (e.g., opioid use in severe, chronic, intractable pain).

4. Symptoms persist for ≥ 1 year despite ALL the following medical management:
   a. Dietary modification
   b. Refractory to, intolerant to, or has contraindications to the use of at least one drug from *both* of the following classes:
      i. Antiemetic medication(s) (e.g., antihistamines, serotonin receptor antagonists, and dopamine receptor antagonists) such as granisetron or ondansetron
      ii. Prokinetic medication(s) (e.g., cholinergic agonists, motilin receptor agonists, and dopamine receptor antagonists) such as metoclopramide

Limitations and Exclusions

Gastric electrical stimulation is considered **experimental, investigational, and unproven** due to insufficient evidence in the peer-reviewed medical literature to establish long-term safety, efficacy, and effect on net health outcomes for **ALL** the following:

1. Treatment of conditions other than chronic refractory gastroparesis including obesity
2. Use in pregnant individuals
3. Use in individuals under 18
4. Temporary GES in which leads are placed endoscopically
5. Concurrent use with glucagon-like peptide-1 (GLP-1) medications

DOCUMENTATION REQUIREMENTS. Molina Healthcare reserves the right to require that additional documentation be made available as part of its coverage determination; quality improvement; and fraud; waste and abuse prevention processes. Documentation required may include, but is not limited to, patient records, test results and credentials of the provider ordering or performing a drug or service. Molina Healthcare may deny reimbursement or take additional appropriate action if the documentation provided does not support the initial determination that the drugs or services were medically necessary, not investigational, or experimental, and otherwise within the scope of benefits afforded to the member, and/or the documentation demonstrates a pattern of billing or other practice that is inappropriate or excessive.

SUMMARY OF MEDICAL EVIDENCE

Gastroparesis

Evidence in published peer-reviewed medical literature examining the safety and efficacy of permanent gastric electrical stimulation (GES) for the treatment of refractory gastroparesis consists of observational studies, case series, retrospective studies, and a small number of randomized controlled trials. Because certain medications—including glucagon-like peptide-1 (GLP-1) receptor agonists such as semaglutide—can slow gastric emptying and produce gastroparesis-like symptoms that often resolve after discontinuation, it is essential to confirm true refractory disease with a medication-free gastric emptying study prior to considering GES implantation (Chaudry et al. 2024). A published case report described resolution of delayed gastric emptying and symptom improvement within six weeks of stopping weekly semaglutide, underscoring the need for an adequate medication washout period before testing (Kalas et al. 2021).

Randomized Controlled Trials

Ducrotte et al. (2020) conducted a large, multicenter, randomized, double-blind, crossover trial (NCT00903799) that studied the efficacy of GES using the Enterra device in patients with chronic (>12 months) refractory vomiting, with or without gastroparesis. A total of 172 patients were randomized to double-blind groups that received either 4 months of stimulation or no stimulation, followed by crossover to the alternate treatment. The primary endpoints were vomiting frequency (vomiting score) and quality of life, while secondary endpoints included changes in digestive symptoms, nutritional status, gastric emptying, and glycemic control. Across both phases, vomiting frequency was reduced when stimulation was active compared to when the device was turned off. Among patients with delayed gastric emptying, this reduction reached statistical significance ($P < 0.01$). In contrast, for patients with normal gastric emptying, the reduction in vomiting approached but did not meet statistical significance ($P = 0,05$). Active stimulation did not accelerate gastric emptying and was not associated with improvements in quality of life.

McCallum et al. (2013) performed a prospective, multicenter, double-blind, randomized, crossover study evaluating the efficacy and safety of GES for chronic vomiting in patients with idiopathic gastroparesis. Thirty-two subjects were implanted with the Enterra GES system and initially received 1.5 months of unblinded ON stimulation. Participants were then randomized in a double-blind manner to two consecutive 3-month crossover periods, during which the device was either ON or OFF, followed by 4.5 months of unblinded ON stimulation. The primary endpoint was weekly vomiting frequency (WVF). Significant reductions in WVF were observed during the initial unblinded ON phase (61.2% reduction from baseline, $P < 0.001$) and maintained at the 1-year follow-up (87% reduction, $P < 0.001$). In contrast, the blinded 3-month crossover periods showed only a non-significant difference between ON and OFF phases. The authors suggested this may reflect either a placebo effect or a carryover effect, as the absence of a washout period could have allowed residual benefits of stimulation to persist during the OFF phase.

McCallum et al. (2010) conducted a prospective, multicenter, randomized, controlled, crossover study (NCT00157755) to evaluate the effects of GES with the Enterra system in patients with diabetic gastroparesis. Eligibility criteria included more than 7 episodes of vomiting per week, delayed gastric emptying confirmed by scintigraphy (> 60% retention at 2 hours and > 10% at 4 hours), symptoms lasting at least 12 months, and refractoriness or intolerance to prokinetic and antiemetic medications used for a minimum of one month, unless contraindicated. A total of 55 patients with refractory diabetic gastroparesis were enrolled and underwent implantation of the Enterra system. Following implantation, all patients received 6 weeks of stimulation (ON phase), followed by randomization to 3-month crossover periods with the device ON or OFF. This was followed by an additional 4.5 months of unblinded stimulation (ON phase). Results showed a 57% reduction in weekly vomiting frequency (WVF) compared with baseline during the initial ON period ($P < 0.001$), which was maintained at one year with a 67.8% reduction ($P < 0.001$). However, during the blinded 3-month crossover phase, there was no significant difference in WVF between the ON and OFF groups.

Abell et al. (2003) conducted an early randomized, double-blind crossover trial evaluating GES for medically refractory gastroparesis. Thirty-three patients aged 19 to 65 years (17 diabetic, 16 idiopathic) were enrolled. Eligibility criteria included more than 7 episodes of vomiting per week, delayed gastric emptying confirmed by scintigraphy (>60% retention at 2 hours and >10% at 4 hours), presence of symptoms for 12 months or greater, and refractoriness or intolerance to at least two of three classes of prokinetic drugs and two of three classes of antiemetics. After implantation, patients were randomized to stimulation ON or OFF for one month in a crossover design. Following this blinded phase, all participants received unblinded stimulation and were reassessed at 6 and 12 months. The primary outcomes evaluated were vomiting frequency, patient preference for ON vs. OFF, upper gastrointestinal symptoms, quality of life, gastric emptying, and adverse events. During the initial double-blind period, subjects reported significantly reduced vomiting in the ON period as opposed to the OFF ($P < 0.05$), with patient preference aligning with these results. In the open-label phase, participants continued to demonstrate significant reductions in vomiting frequency at both 6 and 12 months ($P < 0.05$). Complications including infection led to explanation or revision of the device in five patients.

Systematic Reviews and Meta-Analyses

Rajamanuri et al. (2021) performed a systematic review of literature published over the prior 10 years examining gastroparesis and GES. A total of 12 studies were included in the analysis. Overall, the evidence suggested that GES was effective in reducing symptoms of gastroparesis in adults (pediatric populations were excluded). Reported benefits included improvements in nausea, vomiting, abdominal bloating, weight loss, and quality of life (QOL). Many studies showed significant gains in QOL and Gastroparesis Cardinal Symptom Index (GCSI) scores, though some reported no substantial QOL improvement. Several studies also noted significant weight gain following therapy. Meta-analyses

and randomized controlled trials (RCTs), compared with open-label studies, tended to show more consistent positive outcomes for QOL. Additional observed benefits included reduced inflammatory markers, improved insulin levels in diabetic patients, and shorter hospital stays. The authors concluded that while gastric pacemakers demonstrate variable effects across symptoms, the overall evidence indicates potential efficacy. However, they emphasized the need for further RCTs, particularly evaluating idiopathic and post-surgical gastroparesis.

Levinthal and Bielefeldt (2017) conducted a systematic review and meta-analysis evaluating the effectiveness of GES in gastroparesis. Five randomized controlled studies compared periods with the device ON versus OFF and found no significant difference in total symptom severity (TSS) scores between conditions (P = 0.15). In contrast, 16 open-label studies demonstrated a substantial reduction in TSS (P < 0.001). When comparing treatment modalities, symptom improvements were also observed with medical therapy, placebo arms, and botulinum toxin injections. The authors also noted considerable variability in baseline symptom severity across studies, which strongly influenced treatment outcomes. This heterogeneity limits the ability to draw definitive conclusions regarding the true efficacy of GES.

Non-Randomized Studies, Retrospective Reviews, and Other Evidence
Gourcerol et al. (2023) completed an observational study comparing gastric electrical stimulation (GES) to gastric perioral endoscopic myotomy (G-POEM) in patients with nausea and vomiting from gastroparesis. Sixty-four patients with medically refractory gastroparesis with nausea and vomiting were included in the study. Data was aggregated from the Enterra cohort and the G-POEM cohort. Both independent open-labeled cohorts followed patients for 24 months. Of the 64 patients included in the study, (n=34) were treated with GES and (n=30) were treated with G-POEM. The authors defined the clinical response as a decrease of ≥1 point in the nausea and vomiting score and the absence of a switch from one to the other technique before the end of the 24 months. Clinical response was noted in 21/34 (61.7%) in patients treated with GES and in 21/30 (70%); p=0.60) patients treated with G-POEM. At the 24 month follow up, mean scores of nausea and vomiting subscale decreased in the GES cohort (from 3.0 to 1.6; p=0.001) as well at the G-POEM cohort (from 2.6 to 1.2; p=0.001). However, when adjusted from baseline (0.28 [-0.77; 0.19]; p=0.24) there was no difference between the groups. At 24 months the authors did not see a significant difference in the efficacy of GES and G-POEM with medically refractive gastroparesis with predominant nausea and vomiting. Both cohorts had improved symptomatic and quality of life scores at 24 months. The authors noted several limitations to the study. Patients treated with GES had higher nausea and vomiting sub scores and worse quality of life at baseline as compared to the patients treated with G-POEM, however other characteristics were comparable. There was a lack of randomization and blinding, a small sample size and different scales were used between the two cohorts. At the conclusion of the study, it remains unknow if GES or G-POEM is more effective for gastroparesis with refractory nausea and vomiting.

Heckert et al. (2016) performed a single-center prospective study on the effectiveness of the Enterra system in patients with refractory gastroparesis. A total of 151 patients (72 diabetic, 73 idiopathic, 6 others) underwent implantation and were followed for a mean of 1.4 years. Symptom response was assessed using the Patient Assessment of Upper Gastrointestinal Disorders Symptom Severity Index (PAGI-SYM) and the Clinical Patient Grading Assessment Scale (CPGAS). Of the 138 patients who completed follow-up, 75% reported improvement and 43% achieved at least moderate improvement. Clinical benefit was observed in both diabetic and idiopathic patients, though outcomes were significantly better in the diabetic subgroup (mean CPGAS 3.5 vs. 1.5; p < 0.05). The symptoms most improved were nausea, early satiety, and loss of appetite, with vomiting also improving—particularly among diabetic patients. The authors concluded that GES can provide meaningful symptom relief for a substantial proportion of patients with refractory gastroparesis, with diabetic patients demonstrating a greater likelihood of clinical response.

Gourcerol et al. (2012) conducted a prospective study to evaluate the long-term impact of GES on nausea and vomiting in patients with chronic, intractable nausea and vomiting. The study included patients with both delayed and normal gastric emptying. Thirty-one patients were enrolled in implanted with a GES system. Evaluations were conducted at baseline, 6 months, and 5 years after implantation. Four patients were lost to follow-up, 6 had the devices explanted due to lack of improvement, and 1 patient died. Out of the 20 patients evaluated over 5 years, the quality-of-life score showed 27% improvement (p < 0.01), including nausea (62%; p < 0.01), vomiting (111%; p = 0.03), satiety (158%; p < 0.01), bloating (67%; p < 0.01) and epigastric pain (43%; p = 0.03). Patients with delayed gastric emptying and normal gastric emptying before surgery had an improvement rate of 60% and 50%, respectively. Notably, the 6 patients who had the devices explanted due to lack of improvement were not included in the calculations.

Obesity

There is insufficient published evidence to support the efficacy and safety of GES therapy for promoting weight loss among patients with morbid obesity. Small clinical trials have reported positive outcomes in weight loss and maintenance of weight loss along with minimal complications. The most notable trial, the SHAPE trial, evaluated the difference in the percentage of excess weight loss (EWL) between the control and treatment groups and found EWL was the same for both groups.

Shikora et al. (2009) conducted a prospective, randomized, placebo-controlled, double-blind, multicenter study (NCT00200083) called The SHAPE trial compared implantable gastric stimulation therapy with a standard diet and behavioral therapy regimen in 190 participants with obesity by evaluating the difference in the percentage of EWL between the control and treatment groups. All patients underwent implantation with the implantable gastric stimulator and were randomized to 1 of 2 treatment groups: the control group (stimulation off) or treatment group (stimulation on). The patients were evaluated monthly. All individuals who enrolled in this study agreed to consume a diet with a 500-kcal/d deficit and to participate in monthly support group meetings. The procedure resulted in no deaths and a low complication rate. The primary endpoint of a difference in weight loss between the treatment and control groups was not met. The control group lost 11.7% +/- 16.9% of excess weight and the treatment group lost 11.8% +/- 17.6% (P = .717) according to an intent-to-treat analysis. The authors noted that although implantable gastric stimulation as a surgical option for the treatment of morbid obesity is a less complex procedure than current bariatric operations, the results of the present study do not support its application.

National and Specialty Organizations

In 2022 the **American College of Gastroenterology** (ACG) updated the 2013 ACG guideline on gastroparesis. The ACG presents this guideline as the official practice recommendations of the American College of Gastroenterology. Recommendation 15 states: “Gastric electric stimulation (GES) may be considered for control of GP symptoms as a humanitarian use device (HUD) (conditional recommendation, low quality of evidence)” (Camilleri et al. 2022).

The **National Institute of Diabetes and Digestive and Kidney Diseases** (2018) states that GES may be effective for some patients whose nausea and vomiting do not improve with dietary changes or medications.

The **National Institute for Health and Care Excellence** (2014) published guidance on gastro-electrical stimulation for gastroparesis noting that current evidence on efficacy and safety supports the use of GES as a treatment for chronic, intractable nausea and vomiting due to gastroparesis.

CODING & BILLING INFORMATION

CPT (Current Procedural Terminology)

Code	Description
43647	Laparoscopy, surgical; implantation or replacement of gastric neurostimulator electrodes, antrum
43648	Laparoscopy, surgical; revision or removal of gastric neurostimulator electrodes, antrum
43881	Implantation or replacement of gastric neurostimulator electrodes, antrum, open
43882	Revision or removal of gastric neurostimulator electrodes, antrum, open
64590	Insertion or replacement of peripheral, sacral, or gastric neurostimulator pulse generator or receiver, requiring pocket creation and connection between electrode array and pulse generator or receiver
64595	Revision or removal of peripheral, sacral, or gastric neurostimulator pulse generator or receiver, with detachable connection to electrode array
95980	Electronic analysis of implanted neurostimulator pulse generator system (e.g., rate, pulse amplitude and duration, configuration of wave form, battery status, electrode selectability, output modulation, cycling, impedance and patient measurements) gastric neurostimulator pulse generator/transmitter; intraoperative, with programming
95981	Electronic analysis of implanted neurostimulator pulse generator system (e.g., rate, pulse amplitude and duration, configuration of wave form, battery status, electrode selectability, output modulation, cycling, impedance and patient measurements) gastric neurostimulator pulse generator/transmitter; subsequent, without reprogramming
95982	Electronic analysis of implanted neurostimulator pulse generator system (e.g., rate, pulse amplitude

	and duration, configuration of wave form, battery status, electrode selectability, output modulation, cycling, impedance and patient measurements) gastric neurostimulator pulse generator/transmitter; subsequent, with reprogramming

HCPCS (Healthcare Common Procedure Coding System)

Code	Description
C1767	Generator, neurostimulator (implantable), non-rechargeable
C1778	Lead, neurostimulator (implantable)
L8679	Implantable neurostimulator, pulse generator, any type
L8680	Implantable neurostimulator electrode, each
L8688	Implantable neurostimulator pulse generator, dual array, non-rechargeable, includes extension

CODING DISCLAIMER. Codes listed in this policy are for reference purposes only and may not be all-inclusive. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement. Listing of a service or device code in this policy does not guarantee coverage. Coverage is determined by the benefit document. Molina adheres to Current Procedural Terminology (CPT®), a registered trademark of the American Medical Association (AMA). All CPT codes and descriptions are copyrighted by the AMA; this information is included for informational purposes only. Providers and facilities are expected to utilize industry standard coding practices for all submissions. When improper billing and coding is not followed, Molina has the right to reject/deny the claim and recover claim payment(s). Due to changing industry practices, Molina reserves the right to revise this policy as needed.

APPROVAL HISTORY

10/08/2025	Policy reviewed. Added criteria specification that member must be free of any medication that can cause gastroparesis at least 2 months prior to gastric emptying study. Added GLP-1 as a contraindication to GES. Updated Overview, Summary of Medical Evidence, and References. IRO Peer Review on September 30, 2025 by a practicing physician board-certified in Internal Medicine, Gastroenterology.
10/09/2024	Policy reviewed, no changes to criteria. Updated Overview, Summary of Evidence, and References.
10/12/2023	Policy reviewed, no changes to criteria. Updated Overview and Summary of Evidence due to retirement of policy MCP 243.
06/14/2023	Policy reviewed, no changes to criteria. Updated Summary of Medical Evidence and Reference sections.
06/08/2022	New policy. IRO peer reviewed in May 2022 by a board-certified physician practicing in Gastroenterology.

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APPENDIX

Reserved for State specific information. *Information includes, but is not limited to, State contract language, Medicaid criteria and other mandated criteria.*

This policy contains prior authorization requirements.