Molina Clinical Policy
Gastric Electrical Stimulation: Policy No. 414

Last Approval: 10/12/2023
Next Review Due By: October 2024

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

Gastroparesis, or delayed gastric emptying, is a condition in which the stomach fails to empty its contents at a normal rate, which may lead to symptoms including bloating, discomfort, nausea, vomiting, and early satiety. In severe cases, these symptoms can lead to weight loss, dehydration, electrolyte disturbances, and/or malnutrition. Conservative treatments for gastroparesis include medication, glycemic control in the case of diabetes, and dietary modification. Supportive measures such as intravenous hydration or nutritive support may be needed. When conservative management fails to relieve symptoms, the condition may be referred to as refractory (Hasler 2022).

Gastric electrical stimulation (GES) is a treatment for refractory gastroparesis which involves implantation of electrodes into the gastric muscles at the greater curvature of the stomach. The electrodes are attached to a small, battery-powered pulse generator placed within a subcutaneous pocket in the abdominal area and programmed remotely to optimize therapy for the individual patient. The procedure is usually performed laparoscopically, although an open approach is available when laparoscopic placement is not an option. Once placed, the generator is programmed to send electric pulses to the stomach muscle wall (Shanker et al, 2021; Hasler 2022).

The mechanism of action of GES in the treatment of gastroparesis is not fully understood. Initially, it was thought that the electrical impulses may improve the rate of gastric emptying, however studies have not shown this to be consistently true. Reduction of symptoms in patients with refractory gastroparesis may be due to neurostimulation travelling to the brain from the stomach via the vagal afferents and affecting the nausea and vomiting centers of the brain. It has also been noted that patients treated with GES appear to have an increased gastric accommodation, which could theoretically lead to symptom relief (Shanker et al. 2021; Hasler 2022).

The GES system, now the Enterra™ Therapy System (Medtronic, Inc.), received approval from the United States Food and Drug Administration (FDA) under the Humanitarian Device Exemption in 2000 as indicated for treatment of chronic, intractable nausea and vomiting secondary to gastroparesis of diabetic or idiopathic etiology (FDA 2000). Temporary GES has been investigated as a less invasive trial to determine the potential efficacy of pacing prior to more invasive long-term placement as described above. In temporary GES trials, cardiac pacers placed endoscopically are connected to an external GES device. This is an off-label use, as the only GES configuration currently approved by the FDA uses pacing wires implanted intramuscularly in the antrum of the stomach.

Obesity

Gastric Electrical Stimulation (GES) therapy has been proposed as a treatment for patients with obesity. The goal of GES in treating obesity is to cause early satiety and reduce appetite causing subsequent weight loss. The exact mechanisms that result in changes in eating and behavior are uncertain. There are no GES devices 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. Diagnosis of gastroparesis with diabetic or idiopathic etiology; **AND**
2. 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); **AND**
3. Age 18 or greater; **AND**
4. Symptoms persist for ≥ 1 year despite medical management including:
   a. Dietary modification; **AND**
   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; **AND**
      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 not medically necessary** and may not be authorized for any of 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.

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 GES for the treatment of refractory gastroparesis consists of observational studies, case series, retrospective studies, and a small number of randomized controlled trials. A summary of the most notable studies is below.

An early randomized, double-blind crossover trial enrolled 33 patients ages 19 to 65 years with chronic gastroparesis (17 diabetic, 16 idiopathic) to evaluate the effectiveness of GES on medically refractory gastroparesis. Inclusion criteria required more than 7 episodes of vomiting per week, 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 2 of 3 classes of prokinetic drugs and 2 of 3 classes of antiemetics. After implantation, patients were randomized to stimulation ON or OFF for 1-month periods. The blind was then broken, and all participants were treated with GES and evaluated again at 6 and 12 months. The primary outcomes evaluated were vomiting frequency, preference for ON or OFF, upper gastrointestinal tract 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 ($P<0.05$). Patient preference for the ON period mirrored the vomiting outcome. Unblinded participants reported significantly decreased frequency of vomiting ($P<0.05$) at 6- and 12-month follow up. Infection or other complication resulted in 5

individuals having their GES system explanted or revised (Abell et al. 2003).

A prospective, multicenter, randomized, controlled, crossover study (NCT00157755) conducted by McCallum et al. (2010) evaluated the effects of GES with the Enterra therapy system on symptoms from diabetic gastroparesis. Inclusion criteria required more than 7 episodes of vomiting per week, 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 prokinetic and antiemetic drug classes trialed for at least 1 month unless contra-indicated. Fifty-five patients with refractory diabetic gastroparesis were enrolled and had the Enterra gastric stimulation system implanted. After placement, the stimulator was turned ON for 6 weeks in all patients, followed by randomization to 3-month crossover periods with the device ON or OFF, followed by unblinded ON setting for 4.5 months. There was a significant reduction in weekly vomiting frequency (WVF) of 57% compared to baseline ($P < 0.001$), and at one year remained significant at 67.8% ($P < 0.001$). There was no difference, however, in WVF between patients who had the device ON or OFF during the blinded 3-month crossover period.

McCallum et al. (2013) conducted a similar prospective, multicenter, double-blind, randomized, crossover study evaluating the efficacy and safety of GES in the treatment of chronic vomiting in gastroparesis of idiopathic etiology. Thirty-two subjects were enrolled and had an Enterra GES system implanted and programmed. Stimulation was turned ON for 1.5 months, followed by double-blind randomization to 3-month crossover periods with the device either ON or OFF, followed by unblinded ON stimulation for 4.5 months. The primary outcome evaluated was weekly vomiting frequency (WVF). There was a significant reduction in WVF from baseline in the initial unblinded ON period (61.2%, $P < 0.001$) and at the 1-year follow up (87%, $P < 0.001$). However, the double-blind 3-month periods showed a non-significant reduction in WVF in the ON versus OFF period, raising the question of placebo effect or whether the lack of a washout after the ON period may have allowed for the continued effects of GES to bleed into the OFF period.

A large, multicenter, randomized, double-blind, crossover trial (NCT00903799) studied the efficacy of GES with the Enterra device in patients with chronic (>12 months) refractory vomiting, with or without gastroparesis. Patients (n=172) were then assigned to double-blind groups that received 4 months of stimulation or no stimulation, and then evaluated on the primary outcomes of vomiting score and quality of life, and secondary outcomes of changes in other digestive symptoms, nutritional status, gastric emptying, and glycemic control. During both phases of the crossover, vomiting was reduced in the group with the device on versus with the device off. The reduction in vomiting was statistically significant ($P < 0.01$) when the device was on in patients with delayed gastric emptying, whereas the reduction in vomiting was just above the threshold of statistical significance ($P = 0.05$) for patients with normal gastric emptying. Gastric emptying was not accelerated when the device was on, nor was the device being on associated with increased quality of life (Ducrotte et al. 2020).

A prospective study was conducted by Gourcerol et al. (2012) 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.

Heckert et al. (2016) conducted a single-center prospective study on the effectiveness of GES with the Enterra therapy system for treatment of refractory gastroparesis. A total of 151 patients with refractory gastroparesis (72 diabetic, 73 idiopathic, 6 other) had the Enterra system implanted. The primary outcome was the Clinical Patient Grading Assessment Scale used to assess response based on a patient completed questioner. Of the 138 patients who completed follow up (17 ± 11 months after implantation), symptoms were improved in 75% of patients with 43% being at least moderately improved.

In a systematic review and meta-analysis of evidence on the use of GES for treatment of gastroparesis, Levinthal and Bielefeldt (2017) found that total symptom severity scores decreased significantly in open label studies (n = 16), whereas in the studies in which patients were randomized to periods with or without GES there was no significant difference in total symptom severity scores between the two periods. The analysis also showed there were significant differences in baseline total symptoms severity scores among the available studies which significantly impacted the scores during treatment, calling into question whether accurate conclusions can be drawn from the body of evidence.

Rajamanuri et al. (2021) performed a systemic review on literature published in the last 10 years. A total of 1924 articles were identified in databases (PubMed, PubMed Central, Medline, Science Direct, and Google Scholar). The articles focused on gastroparesis and its symptoms or GES therapy. After screening, 124 articles met initial inclusion and exclusion criteria – 41 articles were found most relevant. For the review, 12 studies were included (review articles, observational studies, and clinical trials). Overall, the studies demonstrated efficacy of the pacemaker on symptoms of gastroparesis in adults (pediatric population excluded). Additional RCTs (Randomized controlled trials) are needed that provide an analysis of the efficacy of gastric pacemakers in improving symptoms of gastroparesis. Future research on the use of gastric pacemakers in idiopathic and post-surgical gastroparesis. The authors concluded that gastric pacemakers have shown differing effects on symptoms (e.g., nausea, vomiting, abdominal bloating, weight loss, and overall quality of life). Significant weight gain from this therapy was also noted in the studies reviewed. Many studies indicated a significant improvement in QOL and Gastroparesis Cardinal Symptom Index scores however, a few reported no substantial change in the QOL following GES. Meta-analysis and RCTs vs. open-label trials indicated positive results for QOL as a result of gastric pacing. The authors note that certain parameters also indicated improvement following GES therapy (e.g., reduction in inflammatory markers, greater insulin levels especially in diabetic patients, and reduced hospital stays).

National and Specialty Organizations

An **American College of Gastroenterology** clinical guideline on management of gastroparesis states that GES may be considered for compassionate treatment in individuals with refractory symptoms of nausea and vomiting (Camilleri et al., 2013).

The **National Institute of Diabetes and Digestive and Kidney Diseases** (2018) states that 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.

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 on a monthly basis. 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.

CODING & BILLING INFORMATION

CPT (Current Procedural Terminology) Codes

CPT	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 or gastric neurostimulator pulse generator or receiver, direct or inductive coupling
64595	Revision or removal of peripheral or gastric neurostimulator pulse generator or receiver
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) Codes

HCPCS	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

10/12/2023 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.*