
Medical Policy



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***Current Policy Effective Date: 11/1/26**
(See policy history boxes for previous effective dates)

Title: Gastric Electrical Stimulation

Description

Gastric electrical stimulation (GES) is performed using a device which consists of a pulse generator, programmed to provide electrical stimulation at different frequencies, connected to intramuscular stomach leads, which are implanted during laparoscopy or open laparotomy. Gastric electrical stimulation is designed to treat chronic drug-refractory nausea and vomiting secondary to gastroparesis of diabetic, idiopathic, or postsurgical etiology. Gastric electrical stimulation has also been investigated as a treatment of obesity. The device may be referred to as a gastric pacemaker.

Medical Policy Statement

Gastric electrical stimulation for the treatment of chronic, intractable (drug refractory) nausea and vomiting due to gastroparesis is established when criteria are met.

Gastric electrical stimulation for the treatment of obesity is experimental/investigational. There is insufficient evidence to determine that the technology results in an improvement in net health outcomes.

Inclusionary and Exclusionary Guidelines

Inclusions:

Gastric electrical stimulation for the treatment of chronic, intractable (drug refractory) nausea and vomiting when **ALL** of the following are met:

- The gastric electrical stimulator is an FDA-approved device (e.g., Enterra™, Enterra™ II);
- Nausea and vomiting are:
 - Secondary to gastroparesis of diabetic or idiopathic etiology; **AND**
 - Refractory to medical management defined by **BOTH** of the following:
 - Failed dietary modification;
 - Failure of **both** antiemetics (anti-nausea/vomiting) **and** prokinetics (anti-reflux) unless pharmaceutical management is contraindicated

Exclusions:

- Criteria are not met
 - Gastric electrical stimulation for gastroparesis of postsurgical etiology
 - Initial treatment of gastroparesis
 - Treatment of obesity
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CPT/HCPCS Level II Codes

Established codes:

43647	43648	43881	43882	64590	64595
95980	95981	95982			

Other codes (investigational, not medically necessary, etc.):

43659	43999
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Notes:

- *Code(s) may not be covered by all contracts or certificates. Please consult customer or provider inquiry resources at BCBSM or BCN to verify coverage.*
 - *Individual policy criteria determine the coverage status of the CPT/HCPCS code(s) on this policy. Codes listed in this policy may have different coverage positions (such as established or experimental/investigational) in other medical policies.*
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Background

Gastroparesis

Gastroparesis is a disorder of gastric motility characterized by delayed emptying of a solid meal. Symptoms include bloating, distension, nausea, and vomiting. When severe and chronic, gastroparesis can be associated with dehydration, poor nutritional status, and poor glycemic control in diabetic patients. While most commonly associated with diabetes, gastroparesis is also found in chronic pseudo-obstruction, connective tissue disorders, Parkinson disease, and psychological pathologic conditions. Some cases may not be associated with an identifiable

cause and are referred to as idiopathic gastroparesis. Gastric electrical stimulation has been investigated as a treatment for gastroparesis.

Obesity

Gastric electrical stimulation has also been investigated as a treatment for obesity. It is used to increase the feeling of satiety with subsequent reduction in food intake and weight loss. The exact mechanisms resulting in changes in eating behavior are uncertain but may be related to neurohormonal modulation and/or stomach muscle stimulation.

Summary of Evidence

For individuals who have gastroparesis who receive gastric electrical stimulation, the evidence includes randomized controlled trials (RCTs), nonrandomized studies and systematic reviews. Relevant outcomes are symptoms and treatment-related morbidity. Several crossover RCTs have been published. Gastric electrical stimulation may be an option for patients with debilitating gastroparesis, which is refractory to medical treatment. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have obesity who receive gastric electrical stimulation, the evidence includes a RCT and several small case series and uncontrolled prospective trials. Relevant outcomes are change in disease status and treatment-related morbidity. The Screened Health Assessment and Pacer Evaluation (SHAPE) trial did not show significant improvement in weight loss using gastric electrical stimulation compared with sham stimulation. There is insufficient evidence to determine that the technology results in an improvement in net health outcomes

Rationale

Evidence reviews assess the clinical evidence to determine whether the use of a technology improves the net health outcome. Broadly defined, health outcomes are length of life, quality of life, and ability to function including benefits and harms. Every clinical condition has specific outcomes that are important to individuals and to managing the course of that condition. Validated outcome measures are necessary to ascertain whether a condition improves or worsens; and whether the magnitude of that change is clinically significant. The net health outcome is a balance of benefits and harms. The following is a summary of the key literature to date.

GASTRIC ELECTRICAL STIMULATION FOR GASTROPARESIS

Systematic Reviews

Several systematic reviews of studies on gastric electrical stimulation for gastroparesis have been published,(1-4) the most recent of which is by Saleem et al (2022).(4) Saleem identified 9 studies (7 RCTs; N=730) including a recent large (N=172) crossover study. The primary outcome evaluated in this analysis was total symptom score. The included studies were deemed of moderate quality and low risk of bias. Analysis of the 7 blind RCTs found the total symptom score was significantly improved at the 4-day, 2-month, 4-month, and 12-month follow-up (mean difference [MD], -6.07; 95% confidence interval [CI], -4.5 to -7.65; p<.00001)

but not at all follow-up time points (not further defined). These studies had high heterogeneity ($I^2=70\%$) due to variable follow-up duration. The weekly vomiting frequency was not different between groups (MD, -1.76; 95% CI, -6.15 to 2.63; $p=.43$) when the blind RCTs were pooled; however, in the open trials, vomiting episodes were lower after gastric electrical stimulation (MD, 15.59; 95% CI, 10.29 to 20.9; $p<.00001$). The analysis is limited by the variety of scoring systems, variable time points of follow up, and relatively small sample sizes of the individual trials.

An older, but more inclusive meta-analysis, was published by Levinthal et al (2017).(1) To be selected for the Levinthal review, studies had to include adults with established gastroparesis, report patient symptom scores and administer treatment for at least 1 week. Five randomized controlled trials (RCTs) and 13 non-RCTs meeting criteria were identified. Pooled analysis of data from the 5 RCTs (N=185) did not find a statistically significant difference in symptom severity when the GES was turned on versus off (standardized mean difference [SMD], 0.17; 95% confidence interval [CI], -0.06 to 0.40; $p=0.15$). Another pooled analysis did not find a statistically significant difference in nausea severity scores when the gastric electrical stimulation was on or off (SMD, -0.143; 95% CI, -0.50 to 0.22; $p=0.45$). In a pooled analysis of 13 open-label single-arm studies and data from open-label extensions of 3 RCTs, mean total symptom severity score decreased 2.68 (95% CI, 2.04 to 3.32) at follow-up from a mean of 6.85 (95% CI, 6.28 to 7.42) at baseline. The rate of adverse events in the immediate postoperative period (reported in 7 studies) was 8.7% (95% CI, 4.3% to 17.1%). The in-hospital mortality rate within 30 days of surgery was 1.4% (95% CI, 0.8% to 2.5%), the rate of reoperations (up to 10 years of follow-up) was 11.1% (95% CI, 8.7% to 14.1%), and the rate of device removal was 8.4% (95% CI, 5.7% to 12.2%).

Randomized Controlled Trials

Ducrotte et al (2020) evaluated permanent GES (Enterra) in a cross-over trial.(5) Patients (N=172) had refractory and chronic vomiting. After GES implantation, patients were randomized to receive stimulation or no stimulation then crossed over to the other treatment after 4 months. The primary endpoints were vomiting score (range 0 to 4 where 0 is daily vomiting and 4 is no vomiting) and the Gastrointestinal Quality of Life Index. The median vomiting score with device on was 2 versus 1 with the device off ($p<.002$); however, over 50% of patients reported similar vomiting scores during the on and off period. There was no difference between groups in the quality of life measure (73.3 on the on phase and 71.1 in the off; $p=.06$). Delayed gastric emptying was not different in the on versus off period. Limitations of this trial include use of an unvalidated scale for the primary endpoint, inclusion of only refractory patients, and 4-month duration of treatment. Importantly, this trial was not limited to patients with gastroparesis.

Abell et al (2003) reported findings from the Worldwide Anti-Vomiting Electrical Stimulation Study (WAVESS).(6) This randomized, placebo-controlled, double-blinded crossover study initially described in the U.S. Food and Drug Administration materials, included 33 patients (17 diabetic and 16 idiopathic) with medically refractory idiopathic or diabetic gastroparesis.(7) Outcome measures were vomiting frequency, preference for stimulation on or stimulation off, upper gastrointestinal tract symptoms, quality of life, gastric emptying, and adverse events. In the initial phase of the study, all patients underwent implantation of the stimulator and were randomly and blindly assigned to stimulation on or stimulation off for the first month. The blind was then broken and all patients were programmed to stimulation on and evaluated at 6 and 12 months. In the double-blind portion of the study, self-reported vomiting frequency was

significantly reduced in the ON vs OFF period ($p < .05$) and this symptomatic improvement was consistent with the significant patient preference ($p < .05$) for the ON vs OFF period determined before breaking the blind. In the unblinded portion of the study, vomiting frequency decreased significantly ($p < .05$) at 6 and 12 months in both the idiopathic and diabetic subgroups. Scores for symptom severity and quality of life significantly improved ($p < .05$) at 6 and 12 months, whereas gastric emptying was only modestly accelerated.

McCallum et al (2010) reported on a crossover RCT evaluating gastric electrical stimulation (Enterra device) in patients with chronic intractable nausea and vomiting from diabetic gastroparesis (DGP).⁽⁸⁾ In this trial, 55 patients with refractory diabetic gastroparesis (5.9 years of diabetic gastroparesis) were given Enterra implants. After surgery, all patients had the stimulator turned on for 6 weeks and then were randomized to groups that had consecutive 3-month crossover periods with the device on or off. After this period, the device was turned on in all patients, and they were followed unblinded for 4.5 months. During the initial 6-week phase with the stimulator turned on, the median reduction in weekly vomiting frequency compared with baseline was 57%. There was no significant difference in weekly vomiting frequency between patients who had the device turned on or off during the 3-month crossover period. At 1 year, the weekly vomiting frequency of all patients was significantly lower than baseline values (median reduction, 68%; $p < .001$). One patient had the device removed due to infection; 2 patients required surgical intervention for lead-related problems.

McCallum et al (2013) evaluated gastric electrical stimulation (Enterra system) in patients with chronic vomiting due to idiopathic gastroparesis in a randomized, double-blind crossover trial.⁽⁹⁾ In this trial, 32 patients with nausea and vomiting associated with idiopathic gastroparesis, unresponsive or intolerant to prokinetic and antiemetic drugs, received Enterra implants and had the device turned on for 6 weeks. Subsequently, 27 of these patients were randomized to have the device turned on or off for 2 consecutive 3-month periods. Twenty-five of these subjects completed the randomized phase; of note, 2 subjects had the device turned on early, 2 subjects had randomization assignment errors, and 1 subject had missing diaries. During the initial 6 week on period, all subjects showed improvements in their weekly vomiting frequency, demonstrating a median reduction of 61.2% (5.5 episodes/week) compared with baseline (17.3 episodes/week; $p < .001$). During the on-off crossover phase, subjects demonstrated no significant differences between the on and off phases for the study's primary endpoint, median weekly vomiting frequency (median 6.4 in on-phase vs 9.8 in off-phase; $p = 1.0$). Among the 19 subjects who completed 12 months of follow up, there was an 87.1% reduction in median weekly vomiting frequency (2 episodes/week) compared with baseline (17.3 episodes/week; $p < .001$). Two subjects required surgical intervention for lead migration/dislodgement or neurostimulator migration.

Nonrandomized Studies

Samaan et al (2022) compared GES to laparoscopic gastrectomy in a retrospective, single-center analysis.⁽¹⁰⁾ Overall, 130 refractory patients underwent GES while 51 received laparoscopic gastrectomy. Patients receiving GES were less likely to report symptom improvement compared with gastrectomy (odds ratio [OR], 0.16; 95% CI, 0.048 to 0.532) over a mean follow-up period of 35 months. However, patients receiving gastrectomy had greater in-hospital morbidity (18% vs. 5%; $p = .017$) and longer hospital stays (9 days vs. 3 days; $p < .001$). The authors concluded that further study was needed to determine which patients might benefit from operative treatment of refractory gastroparesis.

Laine et al (2018) published a retrospective, multicenter analysis of patients with severe, medically refractory gastroparesis who received gastric electrical stimulation.(11) Fourteen patients (11 diabetic, 1 idiopathic, and 2 postoperative) treated in Finland between 2007 and 2015 were included; median follow-up was 3 years. Eight (57.1%) patients experience marked relief of gastroparesis symptoms, while 3 (21.4%) patients experience partial relief. There was a median weight gain of 5.1 kg in 11 (78.6%) patients after gastric electrical stimulation implantation, and, at last possible follow-up, 5 out of 10 (50%) patients were without medication for gastroparesis.

Shada et al (2018) published a prospective study of patients with medically refractory gastroparesis who underwent implantation of gastric electrical stimulation between 2005 and 2016.(12) One hundred nineteen patients (64 diabetic, 55 idiopathic), with mean follow-up of 39.0 ± 32.0 months, were included in the analysis. Before gastric electrical stimulation placement, operatively placed feeding tubes were present in 22% of diabetic and 17% of idiopathic patients, however, after gastric electrical stimulation placement, 67% of feeding tubes were removed. Due to a perceived lack of benefit, 8 patients decided to have their gastric electrical stimulation device removed after a mean time of 36 ± 29 months. Also, there was significant improvement in gastroparesis cardinal symptom index scores for both diabetic ($p=.01$) and idiopathic ($p=.003$) subgroups at ≥ 2 years after implantation. The study was limited by its retrospective nature, not all patients being administered the Gastroparesis Cardinal Symptom Index before GES, and a number of patients being lost to follow-up.

Section Summary: Gastric Electrical Stimulation for Gastroparesis

Many nonrandomized studies and several crossover RCTs have assessed gastric electrical stimulation for treating gastroparesis. Patients generally reported improved symptoms at follow-up including total symptom score, gastric emptying, quality of life and median days in the hospital. The efficacy of gastric electrical stimulation in significantly reducing vomiting frequency and gastrointestinal symptoms and improving quality of life in medically refractory idiopathic or diabetic gastroparesis was supported by the reported data.

GASTRIC ELECTRICAL STIMULATION FOR OBESITY

A single RCT has evaluated the use of GES for treating obesity: the Screened Health Assessment and Pacer Evaluation (SHAPE) trial. Shikora et al (2009) reported on a double-blind RCT that assessed GES for the treatment of obesity.(13) All 190 trial participants received an implantable gastric stimulator and were randomized to have the stimulator turned on or off. All patients were evaluated monthly, participated in support groups, and reduced their dietary intake by 500 kcal/d. At 12-month follow-up, there was no statistically significant difference in excess weight loss between the treatment group (weight loss, 11.8%) and the control group (weight loss, 11.7%) using intention-to-treat analysis ($p=.717$).

Small case series and uncontrolled prospective trials (2002 to 2004) have reported positive outcomes for weight loss and maintenance of weight loss along with minimal complications. (14-19) However, interpretation of these uncontrolled studies is limited.

Section Summary: Gastric Electrical Stimulation for Obesity

For individuals who have obesity who receive GES, the evidence includes an RCT as well as several small case series and uncontrolled prospective trials, which reported positive outcomes. The SHAPE trial did not show significant improvement in weight loss using GES compared with sham stimulation.

Supplemental Information

PRACTICE GUIDELINES AND POSITION STATEMENTS

American College of Gastroenterology

The American College of Gastroenterology (2022) published practice guideline on the management of gastroparesis.(20) The College recommended:

"Gastric electric stimulation (GES) may be considered for control of GP [gastroparesis] symptoms as a humanitarian use device (HUD) (conditional recommendation, low quality of evidence)."

American Gastroenterological Association

In 2025, the American Gastroenterological Association (AGA) published practice guidelines on the management of gastroparesis.(21,23) They recommended that "In patients with gastroparesis refractory to medical therapy, the AGA suggests against the routine use of gastric electrical stimulation". Through shared decision-making, patients and clinicians who prioritize the potential benefits of reducing nausea and vomiting over the possible risks of adverse events may reasonably choose to proceed with GES placement. For implementation considerations for this recommendation, the AGA states that this procedure should be considered only for carefully selected patients with gastroparesis that does not respond to medical therapy. When implemented, patients should be advised that GES is primarily intended to alleviate nausea and vomiting, rather than abdominal pain.

National Institute for Health and Care Excellence

The National Institute for Health and Care Excellence (2014) issued guidance on gastroelectrical stimulation for gastroparesis.(22) The institute made the following recommendations:

- Current evidence on the efficacy and safety of gastric electrical stimulation for gastroparesis is adequate to support the use of this procedure with normal arrangements for clinical governance, consent and audit.
- "... clinicians should inform patients considering gastric electrical stimulation for gastroparesis that some patients do not get any benefit from it. They should also give patients detailed written information about the risk of complications, which can be serious, including the need to remove the device."
- "Patient selection and follow-up should be done in specialist gastroenterology units with expertise in gastrointestinal motility disorders, and the procedure should only be performed by surgeons working in these units."

U.S. PREVENTIVE SERVICES TASK FORCE RECOMMENDATIONS

Not applicable

Ongoing and Unpublished Clinical Trials

Some currently unpublished trials that might influence this review are listed below.

Table 1. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
Ongoing			
NCT03123809	Gastric Electrical Stimulation (GES) and Pyloroplasty for the Treatment of Gastroparesis (GES + PP)	50	Sept 2024
NCT05980455 ^a	Randomized Study of Enterra Programming with Nocturnal Cycling in Gastroparetics	50	Dec 2025

NCT: national clinical trial.

^aDenotes industry-sponsored or cosponsored trial.

Regulatory Status

In 2015, the Gastric Electrical Stimulator system (now called Enterra™ Therapy System; Medtronic) was approved by the U.S. Food and Drug Administration (FDA) through the humanitarian device exemption process (H990014) for the treatment of chronic, intractable (drug refractory) nausea and vomiting secondary to gastroparesis of diabetic or idiopathic etiology.

In 2015, there was a labeling change under H990014 S105 from Enterra™ to the Enterra™/Enterra™ II therapy systems; the treatment indication remained the same, for patients aged 18 to 70 years. The Enterra™ II has a battery life indicator, updated programming software, and better resistance against electrical interference.

No gastric electrical stimulator devices have been approved by the FDA for the treatment of obesity.

Government Regulations

National:

There is no National Coverage Determination for gastric electrical stimulation for the treatment of gastroparesis or obesity.

Local:

There is no Local Coverage Determination for gastric electrical stimulation for the treatment of gastroparesis or obesity.

Medicare may cover devices that have FDA Humanitarian Device Exemption (HDE) if specific criteria are met.

(The above Medicare information is current as of the review date for this policy. However, the coverage issues and policies maintained by the Centers for Medicare & Medicaid Services [CMS, formerly HCFA] are updated and/or revised periodically. Therefore, the most current CMS information may not be contained in this document. For the most current information, the reader should contact an official Medicare source.)

Related Policies

N/A

References

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12. Shada A, Nielsen A, Marowski S, et al. Wisconsin's Enterra Therapy Experience: A multi-institutional review of gastric electrical stimulation for medically refractory gastroparesis. *Surgery*. Oct 2018;164(4):760-765. PMID 30072246
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The articles reviewed in this research include those obtained in an Internet based literature search for relevant medical references through 6/30/26, the date the research was completed.

Joint BCBSM/BCN Medical Policy History

Policy Effective Date	BCBSM Signature Date	BCN Signature Date	Comments
7/1/13	4/16/13	4/22/13	Joint policy established
1/1/15	10/24/14	11/3/14	Routine maintenance
1/1/16	10/13/15	10/27/15	Routine maintenance
1/1/17	10/11/16	10/11/16	Routine maintenance
1/1/18	10/19/17	10/19/17	Routine maintenance
1/1/19	10/16/18	10/16/18	Routine maintenance
11/1/20	10/6/20		GES established with criteria
11/1/21	8/17/21		Routine maintenance
11/1/22	8/16/22		Routine maintenance
11/1/23	8/15/23		Routine maintenance (slp) Vendor Managed: N/A
11/1/24	8/20/24		Routine maintenance (slp) Vendor Managed: N/A
11/1/25	8/19/25		Routine maintenance (ls) Vendor Managed: N/A Format updated
11/1/26	8/18/26		Routine maintenance (slp/mk) Vendor Managed: N/A

Next Review Date: 3rd Qtr, 2027

BLUE CARE NETWORK BENEFIT COVERAGE
POLICY: GASTRIC ELECTRICAL STIMULATION

Coverage Determination:

Commercial HMO (includes Self-Funded groups unless otherwise specified)	Covered; criteria applies
BCNA (Medicare Advantage)	Refer to the Medicare information under the Government Regulations section of this policy.
BCN65 (Medicare Complementary)	Coinsurance covered if primary Medicare covers the service.