7.01.73	Gastric Electrical Stimulation		
Original Policy Date:	December 7, 2006	**Effective Date:**	April 1, 2025
Section:	7.0 Surgery	**Page:**	Page 1 of 15

Policy Statement

I. Gastric electrical stimulation is considered **investigational** for the treatment of gastroparesis of diabetic, idiopathic, or postsurgical etiology.

II. Gastric electrical stimulation is considered **investigational** for the treatment of obesity.

NOTE: Refer to Appendix A to see the policy statement changes (if any) from the previous version.

Policy Guidelines

Coding

See the Codes table for details.

Description

Gastric electrical stimulation (GES) is performed using an implantable device designed to treat chronic drug-refractory nausea and vomiting secondary to gastroparesis of diabetic, idiopathic, or postsurgical etiology. GES has also been investigated as a treatment of obesity. The device may be referred to as a gastric pacemaker.

Summary of Evidence

For individuals who have gastroparesis who receive gastric electrical stimulation (GES), 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. A 2017 meta-analysis of 5 RCTs did not find a significant benefit of GES on the severity of symptoms associated with gastroparesis. Patients generally reported improved symptoms at follow-up whether or not the device was turned on, suggesting a placebo effect. A 2022 meta-analysis did find some improvements, but interpretation of its findings are limited by inconsistent benefits across different outcomes and timepoints, high heterogeneity (I^2=70%), and inclusion of study populations not representative of the intended population. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have obesity who receive GES, the evidence includes an 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 GES compared with a sham stimulation. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Additional Information

Not applicable.

Related Policies

- N/A

Benefit Application

Benefit determinations should be based in all cases on the applicable contract language. To the extent there are any conflicts between these guidelines and the contract language, the contract language will control. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

Some state or federal mandates (e.g., Federal Employee Program [FEP]) prohibits plans from denying Food and Drug Administration (FDA)-approved technologies as investigational. In these instances, plans may have to consider the coverage eligibility of FDA-approved technologies on the basis of medical necessity alone.

Regulatory Status

In 2000, 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 gastroparesis. The GES system consists of 4 components: the implanted pulse generator, 2 unipolar intramuscular stomach leads, the stimulator programmer, and the memory cartridge. With the exception of the intramuscular leads, all other components have been used in other implantable neurologic stimulators, such as spinal cord or sacral nerve stimulation. The intramuscular stomach leads are implanted either laparoscopically or during laparotomy and are connected to the pulse generator, which is implanted in a subcutaneous pocket. The programmer sets the stimulation parameters, which are typically set at an "on" time of 0.1 seconds alternating with an "off" time of 5.0 seconds. The Enterra II system features no magnetic activation switch which reduces electromagnetic interference.

Currently, no GES devices have been approved by the FDA for the treatment of obesity. The Transcend® (Transneuronix; acquired by Medtronic in 2005), an implantable gastric stimulation device, is available in Europe for treatment of obesity.

Rationale

Background
Treatment

Gastroparesis
Gastroparesis is a chronic 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 (GES), also referred to as gastric pacing, using an implantable device, has been investigated primarily as a treatment for gastroparesis. Currently available devices consist of a pulse generator, which can be programmed to provide electrical stimulation at different frequencies, connected to intramuscular stomach leads, which are implanted during laparoscopy or open laparotomy (see Regulatory Status section).

Obesity
GES has also been investigated as a treatment of obesity. It is used to increase a 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.

Literature Review

Evidence reviews assess the clinical evidence to determine whether the use of technology improves the net health outcome. Broadly defined, health outcomes are the length of life, quality of life, and ability to function, including benefits and harms. Every clinical condition has specific outcomes that are important to patients and 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.

To assess whether the evidence is sufficient to draw conclusions about the net health outcome of technology, 2 domains are examined: the relevance, and quality and credibility. To be relevant, studies must represent 1 or more intended clinical use of the technology in the intended population and compare an effective and appropriate alternative at a comparable intensity. For some conditions, the alternative will be supportive care or surveillance. The quality and credibility of the evidence depend on study design and conduct, minimizing bias and confounding that can generate incorrect findings. The randomized controlled trial (RCT) is preferred to assess efficacy; however, in some circumstances, nonrandomized studies may be adequate. RCTs are rarely large enough or long enough to capture less common adverse events and long-term effects. Other types of studies can be used for these purposes and to assess generalizability to broader clinical populations and settings of clinical practice.

Promotion of greater diversity and inclusion in clinical research of historically marginalized groups (e.g., People of Color [African-American, Asian, Black, Latino and Native American]; LGBTQIA (Lesbian, Gay, Bisexual, Transgender, Queer, Intersex, Asexual); Women; and People with Disabilities [Physical and Invisible]) allows policy populations to be more reflective of and findings more applicable to our diverse members. While we also strive to use inclusive language related to these groups in our policies, use of gender-specific nouns (e.g., women, men, sisters, etc.) will continue when reflective of language used in publications describing study populations.

Gastric Electrical Stimulation for Gastroparesis

Clinical Context and Therapy Purpose

The purpose of gastric electrical stimulation (GES) is to provide a treatment option that is an improvement on existing therapies, such as conservative management, medication, and enteral or total parenteral nutrition, in individuals with gastroparesis.

The following PICO was used to select literature to inform this review.

Populations

The relevant population of interest is individuals with gastroparesis.

Interventions

The therapy being considered is GES.

Comparators

Comparators of interest include conservative management, medication, and enteral or total parenteral nutrition. Treatment includes diet modification and gut motility stimulation.

Outcomes

The general outcomes of interest are symptoms and treatment-related morbidity.

The existing literature evaluating GES as a treatment for gastroparesis has varying lengths of follow-up, ranging from 6 to 12 months. While studies described below all reported at least 1 outcome of interest, longer follow-up was necessary to fully observe outcomes. Therefore, 10 years of follow-up is considered necessary to demonstrate efficacy.

Study Selection Criteria

Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- To assess longer-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
- Studies with duplicative or overlapping populations were excluded.

Review of Evidence

Systematic Reviews

Several systematic reviews of studies on GES for gastroparesis have been published,[1,2,3,4,] the most recent of which is by Saleem et al (2022). Saleem identified 9 studies (7 RCTs; N=730) including a recent large (N=172) crossover study by Durcotte et al (2020).[4,] The primary outcome evaluated in this analysis was total symptom score (TSS). The included studies were deemed of moderate quality and low risk of bias. Analysis of the 7 blind RCTs found the TSS 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 GES (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 et al review, studies had to include adults with established gastroparesis, report patient symptom scores, and administer treatment for at least 1 week. Five 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, 0.17; 95% CI, -0.06 to 0.40; p=.15). Another pooled analysis did not find a statistically significant difference in nausea severity scores when the GES was on or off (standardized mean difference, -0.143; 95% CI, -0.50 to 0.22; p=.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 to 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

A summary of the larger RCTs included in the meta-analyses is presented below and in Tables 1 and 2. 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 double-blind crossover study, initially described in the U.S. Food and Drug Administration (FDA) materials, included 33 patients with intractable idiopathic or diabetic gastroparesis.[7,] The primary endpoint was a reduction in vomiting frequency, as measured by patient diaries. 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, with crossover to off and on during the second month. Baseline vomiting frequency was 47 episodes per month, which declined in both on and off groups to 23 and 29 episodes, respectively. However, no statistically significant differences were found in the number of vomiting episodes between groups, suggesting a placebo effect. In the second, open-label, phase of the trial, all patients had their stimulators turned on for the remainder of the 6- to 12-month follow-up. During this period, vomiting frequency declined in both the idiopathic and diabetic subgroups.

McCallum et al (2010) reported on a crossover RCT evaluating GES (Enterra device) in patients with chronic intractable nausea and vomiting from diabetic gastroparesis.[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 (WVF) compared with baseline was 57%. There was no significant difference in WVF between patients who had the device turned on or off during the 3-month crossover period. At 1 year, the WVF for all patients was significantly lower than baseline values (median reduction, 68%; p<.001). One patient had the device removed due to infection; 2 required surgical intervention for lead-related problems.

McCallum et al (2013) evaluated GES (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 WVF, 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 WVF (median, 6.4 in on-phase versus 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 WVF (2 episodes/week) compared with baseline (17.3 episodes/week; p<.001). Two subjects required surgical intervention for lead migration/dislodgement or neurostimulator migration.

Table 1. Summary of Key Randomized Controlled Trial Characteristics

Study	Countries	Sites	Dates	Participants	Interventions	
					Active	Comparator
Ducrotte et al (2020)[5,]	France	19	2009-2013	Patients with refractory and chronic nausea and vomiting (N=172)	GES (stimulation on)	GES (stimulation off)
Abell et al (2003) [6,]	U.S., Canada, EU	11	NR	Patients with intractable idiopathic or diabetic	GES (stimulation on)	GES (stimulation off)

Study	Countries	Sites	Dates	Participants	Interventions	
				gastroparesis (N=33)		
McCallum et al (2010) [8,]	U.S.	8	2002-2007	Patients with chronic intractable nausea and vomiting from diabetic gastroparesis (N=55)	GES (stimulation on)	GES (stimulation off)
McCallum et al (2013) [9,]	U.S.	8	2002-2008	Patients with chronic vomiting due to idiopathic gastroparesis (N=32)	GES (stimulation on)	GES (stimulation off)

EU: European Union; GES: gastric electrical stimulation; NR: not reported.

Table 2. Summary of Key Randomized Controlled Trial Results

Study	Weekly Vomiting Frequency	Total Symptom Score	Vomiting Frequency Score
Ducrotte et al (2020)[5,]			
ON (mean ± SD)			2.2 ± 1.7
ON (median)			2
OFF (mean ± SD)			1.8 ± 1.7
OFF (median)			1
p-value			.0009
Abell et al (2003)[6,]			
ON	6.8	12.5 ± 1.0	
OFF	13.5	13.9 ± 1.1	
p -value	<.05	NR	
McCallum et al (2010)[8,]			
ON	3.81		
OFF	4.25		
p -value	.215		
McCallum et al (2013)[9,]			
ON	6.38		
OFF	9.75		
p -value	1.0		

NR: not reported; SD: standard deviation.

The purpose of the limitations tables (see Tables 3 and 4) is to display notable limitations identified in each study. This information is synthesized as a summary of the body of evidence following each table and provides the conclusions on the sufficiency of evidence supporting the position statement.

Table 3. Study Relevance Limitations

Study	Population[a]	Intervention[b]	Comparator[c]	Outcomes[d]	Follow-Up[e]
Ducrotte et al (2020)[5,]	3. Study population not representative of intended use.			4. Not established and validated measurements; 5. Clinically significant difference not prespecified.	1. Not sufficient duration for benefit; 2. Not sufficient duration for harms.
Abell et al (2003)[6,]	2. Study population is unclear.				1. Not sufficient duration for benefit; 2. Not sufficient duration for harms.
McCallum et al (2010)[8,]	2. Study population is unclear.				1. Not sufficient duration for benefit; 2. Not sufficient duration for harms.

Study	Population[a]	Intervention[b]	Comparator[c]	Outcomes[d]	Follow-Up[e]
McCallum et al (2013)[9,]	2. Study population is unclear.				1. Not sufficient duration for benefit; 2. Not sufficient duration for harms.

The study limitations stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.
[a] Population key: 1. Intended use population unclear; 2. Study population is unclear; 3. Study population not representative of intended use; 4. Enrolled populations do not reflect relevant diversity; 5. Other.
[b] Intervention key: 1. Not clearly defined; 2. Version used unclear; 3. Delivery not similar intensity as comparator; 4. Not the intervention of interest.
[c] Comparator key: 1. Not clearly defined; 2. Not standard or optimal; 3. Delivery not similar intensity as intervention; 4. Not delivered effectively.
[d] Outcomes key: 1. Key health outcomes not addressed; 2. Physiologic measures, not validated surrogates; 3. No CONSORT reporting of harms; 4. Not establish and validated measurements; 5. Clinically significant difference not prespecified; 6. Clinical significant difference not supported.
[e] Follow-Up key: 1. Not sufficient duration for benefit; 2. Not sufficient duration for harms.

Table 4. Study Design and Conduct Limitations

Study	Allocation[a]	Blinding[b]	Selective Reporting[c]	Follow-Up[d]	Power[e]	Statistical[f]
Ducrotte et al (2020)[5,]						
Abell et al (2003)[6,]	3. Allocation concealment unclear			3. High number of crossovers	1. Power calculations not reported	
McCallum et al (2010)[8,]				3. High number of crossovers		
McCallum et al (2013)[9,]				3. High number of crossovers		

The study limitations stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.
[a] Allocation key: 1. Participants not randomly allocated; 2. Allocation not concealed; 3. Allocation concealment unclear; 4. Inadequate control for selection bias.
[b] Blinding key: 1. Not blinded to treatment assignment; 2. Not blinded outcome assessment; 3. Outcome assessed by treating physician.
[c] Selective Reporting key: 1. Not registered; 2. Evidence of selective reporting; 3. Evidence of selective publication.
[d] Follow-Up key: 1. High loss to follow-up or missing data; 2. Inadequate handling of missing data; 3. High number of crossovers; 4. Inadequate handling of crossovers; 5. Inappropriate exclusions; 6. Not intent to treat analysis (per protocol for noninferiority trials).
[e] Power key: 1. Power calculations not reported; 2. Power not calculated for primary outcome; 3. Power not based on clinically important difference.
[f] Statistical key: 1. Intervention is not appropriate for outcome type: (a) continuous; (b) binary; (c) time to event; 2. Intervention is not appropriate for multiple observations per patient; 3. Confidence intervals and/or p values not reported; 4.Comparative treatment effects not calculated.

Nonrandomized Studies

Numerous observational studies have been published. Key studies are summarized below.
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 GES.[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 experienced marked relief of gastroparesis symptoms, whereas 3 (21.4%) patients experienced partial relief. There was a median weight gain of 5.1 kg in 11 (78.6%) patients after GES implantation, and at last possible follow-up, 5 out of 10 (50%) patients were without medication for gastroparesis. The study was limited by its retrospective nature, small population size, and relatively short follow-up time.

Shada et al (2018) published a prospective study of patients with medically refractory gastroparesis who underwent implantation of GES 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 GES placement, operatively placed feeding tubes were present in 22% of diabetic and 17% of idiopathic patients; however, after GES placement, 67% of feeding tubes were removed. Due to a perceived lack of benefit, 8 patients decided to have their GES 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 GES for treating gastroparesis. A 2017 meta-analysis of 5 RCTs did not find a significant benefit of GES on the severity of symptoms associated with gastroparesis. Patients generally reported improved symptoms at follow-up whether or not the device was turned on, suggesting a placebo effect. For example, there was no significant difference in the on versus off position in symptom severity or nausea severity scores. A 2022 meta-analysis did find improvement in TSS but is limited by high heterogeneity in follow-up times, and the inclusion of a crossover RCT that included those with chronic, refractory nausea/vomiting rather than limiting to patients with gastroparesis.

Gastric Electrical Stimulation for Obesity

Clinical Context and Therapy Purpose

The purpose of GES is to provide a treatment option that is an alternative to or an improvement on existing therapies, such as conservative management, medication, and bariatric surgery in individuals with obesity.

The following PICO was used to select literature to inform this review.

Populations

The relevant population of interest is individuals with obesity.

Interventions

The therapy being considered is GES.

Comparators

Comparators of interest include conservative management, medication, and bariatric surgery. Treatment includes physical exercise, low carbohydrate dieting, and low-fat dieting.

Outcomes

The general outcomes of interest are change in disease status and treatment-related morbidity. The existing literature evaluating GES as a treatment for obesity has varying lengths of follow-up. While studies described below all reported at least 1 outcome of interest, longer follow-up was necessary to fully observe outcomes. Therefore, 1 year of follow-up is considered necessary to demonstrate efficacy.

Study Selection Criteria

Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- To assess longer-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
- Studies with duplicative or overlapping populations were excluded.

Review of Evidence

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.[14,15,16,17,18,19,] 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

The purpose of the following information is to provide reference material. Inclusion does not imply endorsement or alignment with the evidence review conclusions.

Clinical Input From Physician Specialty Societies and Academic Medical Centers

While the various physician specialty societies and academic medical centers may collaborate with and make recommendations during this process, through the provision of appropriate reviewers, input received does not represent an endorsement or position statement by the physician specialty societies or academic medical centers, unless otherwise noted.

2015 Input

Clinical input was sought to help determine whether the use of gastric electrical stimulation (GES) for individuals with gastroparesis would provide a clinically meaningful improvement in net health outcome and whether the use is consistent with generally accepted medical practice. In response to requests, input was received from 1 specialty society (2 reviewers) and 4 academic centers while this policy was under review in 2015. For individuals who have gastroparesis who receive GES, clinical input does not support a clinically meaningful improvement in net health outcome and does not indicate this use is consistent with generally accepted medical practice. Most respondents agreed that GES should be considered investigational for gastroparesis. There was a lack of consensus whether GES should be considered medically necessary for any specific indication (e.g., diabetic gastroparesis, idiopathic gastroparesis, gastroparesis of postsurgical etiology). The reviewers were not asked about the use of GES for treatment of obesity.

2009 Input

Clinical input was sought to help determine whether the use of GES for individuals with gastroparesis or obesity would provide a clinically meaningful improvement in net health outcome and whether the use is consistent with generally accepted medical practice. In response to requests, input was received from 4 academic medical centers (5 reviewers) while this policy was under review in 2009. For individuals who have gastroparesis or obesity who receive GES, clinical input does not support a clinically meaningful improvement in net health outcome and does not indicate this use is consistent with generally accepted medical practice. There was strong agreement among reviewers about the limited data for the use of GES to treat diabetic and idiopathic gastroparesis and about the need for randomized controlled trials (RCTs). There was strong agreement that GES is investigational in the treatment of obesity.

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 2022, the American College of Gastroenterology updated practice guidelines on the management of gastroparesis.[20,] The College recommended that: "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)."

National Institute for Health and Care Excellence

In 2014, NICE issued guidance on GES for gastroparesis.[21,] The Institute made the following recommendations:

1.1 "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."

1.2 "... 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."

1.3 "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.

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 unpublished trials that might influence this review are listed in Table 5.

Table 5. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
Ongoing			

NCT No.	Trial Name	Planned Enrollment	Completion Date
NCT03123809	Combined Gastric Electrical Stimulation (GES) and Pyloroplasty for the Treatment of Gastroparesis: Can Pyloroplasty be Effective Without GES?	50	Sep 2024
NCT05980455[a]	Randomized Study of Enterra Programming with Nocturnal Cycling in Gastroparetics	50	Dec 2025

NCT: national clinical trial.
[a] Denotes industry-sponsored or cosponsored trial.

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Documentation for Clinical Review

- No records required

Coding

This Policy relates only to the services or supplies described herein. Benefits may vary according to product design; therefore, contract language should be reviewed before applying the terms of the Policy.

The following codes are included below for informational purposes. Inclusion or exclusion of a code(s) does not constitute or imply member coverage or provider reimbursement policy. Policy Statements are intended to provide member coverage information and may include the use of some codes for clarity. The Policy Guidelines section may also provide additional information for how to interpret the Policy Statements and to provide coding guidance in some cases.

Type	Code	Description
CPT®	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

Type	Code	Description
	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	L8680	Implantable neurostimulator electrode, each
	L8685	Implantable neurostimulator pulse generator, single array, rechargeable, includes extension
	L8686	Implantable neurostimulator pulse generator, single array, nonrechargeable, includes extension
	L8687	Implantable neurostimulator pulse generator, dual array, rechargeable, includes extension
	L8688	Implantable neurostimulator pulse generator, dual array, nonrechargeable, includes extension

Policy History

This section provides a chronological history of the activities, updates and changes that have occurred with this Medical Policy.

Effective Date	Action
12/07/2006	New Policy Adoption
04/03/2009	Policy Revision
10/29/2010	Coding update
01/06/2012	Policy revision without position change
03/13/2012	Coding update
11/26/2014	Policy revision without position change
09/30/2015	Coding update
02/01/2016	Coding update
03/01/2016	Policy revision without position change
04/01/2017	Policy revision without position change
04/01/2018	Policy revision without position change
05/01/2019	Policy revision without position change
05/01/2020	Annual review. No change to policy statement. Literature review updated.
04/01/2021	Annual review. No change to policy statement. Literature review updated.
05/01/2022	Annual review. No change to policy statement. Literature review updated.
04/01/2023	Annual review. No change to policy statement. Literature review updated.
03/01/2024	Coding update
04/01/2024	Annual review. No change to policy statement. Literature review updated.
04/01/2025	Annual review. No change to policy statement. Policy guidelines and literature review updated.

Definitions of Decision Determinations

Medically Necessary: Services that are Medically Necessary include only those which have been established as safe and effective, are furnished under generally accepted professional standards to treat illness, injury or medical condition, and which, as determined by Blue Shield, are: (a) consistent with Blue Shield medical policy; (b) consistent with the symptoms or diagnosis; (c) not furnished primarily for the convenience of the patient, the attending Physician or other provider; (d) furnished at the most appropriate level which can be provided safely and effectively to the patient; and (e) 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 the Member's illness, injury, or disease.

Investigational/Experimental: A treatment, procedure, or drug is investigational when it has not been recognized as safe and effective for use in treating the particular condition in accordance with generally accepted professional medical standards. This includes services where approval by the federal or state governmental is required prior to use, but has not yet been granted.

Split Evaluation: Blue Shield of California/Blue Shield of California Life & Health Insurance Company (Blue Shield) policy review can result in a split evaluation, where a treatment, procedure, or drug will be considered to be investigational for certain indications or conditions, but will be deemed safe and effective for other indications or conditions, and therefore potentially medically necessary in those instances.

Prior Authorization Requirements and Feedback (as applicable to your plan)

Within five days before the actual date of service, the provider must confirm with Blue Shield that the member's health plan coverage is still in effect. Blue Shield reserves the right to revoke an authorization prior to services being rendered based on cancellation of the member's eligibility. Final determination of benefits will be made after review of the claim for limitations or exclusions.

Questions regarding the applicability of this policy should be directed to the Prior Authorization Department at (800) 541-6652, or the Transplant Case Management Department at (800) 637-2066 ext. 3507708 or visit the provider portal at www.blueshieldca.com/provider.

We are interested in receiving feedback relative to developing, adopting, and reviewing criteria for medical policy. Any licensed practitioner who is contracted with Blue Shield of California or Blue Shield of California Promise Health Plan is welcome to provide comments, suggestions, or concerns. Our internal policy committees will receive and take your comments into consideration.

For utilization and medical policy feedback, please send comments to: MedPolicy@blueshieldca.com

Disclaimer: This medical policy is a guide in evaluating the medical necessity of a particular service or treatment. Blue Shield of California may consider published peer-reviewed scientific literature, national guidelines, and local standards of practice in developing its medical policy. 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 covered services. Member contracts may differ in their benefits. Blue Shield reserves the right to review and update policies as appropriate.

Appendix A

POLICY STATEMENT (No changes)	
BEFORE	**AFTER**
Gastric Electrical Stimulation 7.01.73 **Policy Statement:** I. Gastric electrical stimulation is considered **investigational** for the treatment of gastroparesis of diabetic, idiopathic, or postsurgical etiology. II. Gastric electrical stimulation is considered **investigational** for the treatment of obesity.	**Gastric Electrical Stimulation 7.01.73** **Policy Statement:** I. Gastric electrical stimulation is considered **investigational** for the treatment of gastroparesis of diabetic, idiopathic, or postsurgical etiology. II. Gastric electrical stimulation is considered **investigational** for the treatment of obesity.