Medical Policy

Blue Cross Blue Shield Blue Care Network of Michigan

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***Current Policy Effective Date: 11/1/24**
(See policy history boxes for previous effective dates)

Title: Gastric Electrical Stimulation

Description/Background

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.

DIAGNOSIS OF GASTROPARESIS

Documented delay in gastric emptying is required for the diagnosis of gastroparesis. Scintigraphic gastric emptying of solids is the standard for the evaluation of gastric emptying and the diagnosis of gastroparesis. The most reliable method and parameter for diagnosis of gastroparesis is gastric retention of solids at 4 h measured by scintigraphy. Studies of shorter duration or based on a liquid challenge result in decreased sensitivity in the diagnosis of gastroparesis.

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, 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.

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.

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 four components: the implanted pulse generator, two 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 a 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 second alternating with an “off” time of 5.0 second. The Enterra II system features no magnetic activation switch which reduces electromagnetic interference.

Currently, no GES devices have been approved by 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.

Medical Policy Statement

Gastric electrical stimulation for the treatment of gastroparesis is established for individuals who meet specified criteria.

Gastric pacing for the treatment of obesity is experimental/investigational. The safety and effectiveness of this procedure have not been established.

Inclusionary and Exclusionary Guidelines

Inclusions:
Gastric electrical stimulation for the treatment of gastroparesis may be considered medically necessary with the use of an FDA approved device (e.g., Enterra™) when ALL of the following criteria have been met:

- Gastroparesis of diabetic or idiopathic etiology
- Refractory to medical management or medical management is contraindicated

- Includes dietary modification or both antiemetics (anti-nausea/vomiting) and prokinetics (anti-reflux)

Exclusions:

- When above criteria are not met
- As an initial treatment for gastroparesis
- For the treatment of obesity

CPT/HCPCS Level II Codes *(Note: The inclusion of a code in this list is not a guarantee of coverage. Please refer to the medical policy statement to determine the status of a given procedure)*

Established codes:

43647	43648	43881	43882	64590	64595
95980	95981	95982			

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

43659	43999

Rationale

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 alternative to or an improvement on existing therapies, such as conservative management, medication, and enteral or total parenteral nutrition, in individuals with gastroparesis.

The following PICOs were used to select literature to inform this review.

Populations
The relevant population of interest are individuals with gastroparesis.

Interventions
The therapy being considered is gastric electrical stimulation.

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 gastric electrical stimulation 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 one 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 gastric electrical stimulation (GES) for gastroparesis have been published,(1-4) the most recent of which is by Saleem et al (2022) Levinthal et al (2017). 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 (I2=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 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 GES 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

A summary of the larger RCTs included in the meta-analyses is presented below.

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-blinded crossover study initially described in a U.S. Food and Drug Administration 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 significant differences were found in the number of vomiting episodes between the 2 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 (DGP).(8) In this trial, 55 patients with refractory DGP (5.9 years of DGP) 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 cross-over periods with the device on or off. After this period, the device was turned on in all patients, and they were followed up 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 of all patients was significantly lower than baseline values (median reduction, 68%; $p<0.001$). One patient had the device removed due to infection; 2 patients required surgical intervention due to 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, two subjects had

randomization assignment errors, and 1 subject had missing diaries. During the initial 6 week on period, all subjects demonstrated 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<0.001). During the on-off crossover phase, subjects demonstrated no significant differences between the on and off phase 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<0.001). Two subjects required surgical intervention for lead migration/dislodgement or neurostimulator migration.

Table 1. Summary of Key RCT Characteristics

Study; Trial	Countries	Sites	Dates	Participants	Interventions	
					Active	Comparator
Ducrotte et al (2020)	France	19	2009-2013	Patients with refractory and chronic nausea and vomiting (N=172)	GES (stimulation on)	GES (stimulation off)
Abell (2003)	US, Canada, EU	11	NR	Patients with intractable idiopathic or diabetic gastroparesis (n=33)	GES (stimulation on)	GES (stimulation off)
McCallum (2010)	US	8	2002-2007	Patients with chronic intractable nausea and vomiting from diabetic gastroparesis (n=55)	GES (stimulation on)	GES (stimulation off)
McCallum (2013)	US	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 RCT Results

Study	Weekly Vomiting Frequency	Total Symptom Score	Vomiting Frequency Score
Ducrotte et al			
ON (mean +/- SD			2.2 ±1.7
ON (median)			2
OFF (mean +/- SD			1.8 ± 1.7
OFF (median)			1
p-value			0.0009
Abell (2003)			
ON	6.8	12.5±1.0	
OFF	13.5	13.9±1.1	
p-value	<0.05	NR	
McCallum (2010)			
ON	3.81		
OFF	4.25		
p-value	0.215		
McCallum (2013)			
ON	6.38		
OFF	9.75		
p-value	1.0		

NR – not reported; SD: standard deviation.

Nonrandomized Studies

Laine et al (2018) published a retrospective, multicenter analysis of patients with severe, medically refractory gastroparesis who received GES.(10) 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 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.(11) 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 GCSI scores for both diabetic (p=0.01) and idiopathic (p=0.003) subgroups at ≥ 2 years after implantation. The study was limited by its retrospective nature, not all patients being administered the GCSI before GES, and a number of patients being lost to follow-up.

The Enterra Therapy System received Humanitarian Device (HDE) use clearance from the FDA in 2000. The data presented to the FDA documented “probable benefit” of Gastric Electrical Stimulation (GES) via the Worldwide Anti-vomiting Electrical Stimulation Study (WAVESS) which evaluated the efficacy of GES in patients with gastroparesis. WAVESS included 33 patients (17 diabetic and 16 idiopathic) who underwent 2 consecutive months of a randomized, placebo-controlled, double-blind, cross-over trial following surgical implant of a GES. A significant reduction in weekly vomiting frequency was reported during the ON phase. At 12 months, more than a 50% improvement in vomiting frequency was reported by 79% of diabetic patients and 77% of idiopathic patients. Seventy-three percent of patients experienced improvements in quality of life.

Section Summary: Gastric Electrical Stimulation for Gastroparesis
Many nonrandomized studies and several crossover RCTs have assessed GES 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. Efficacy of Enterra therapy for severe diabetic gastroparesis patients failing medical therapy was supported by the reported data. Authors conclude that more research is necessary to address unknown factors related to the pathophysiology of this disorder.

GASTRIC ELECTRICAL STIMULATION FOR OBESITY

Clinical Context and Therapy Purpose
The purpose of gastric electrical stimulation 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 patients with obesity.

The following PICOs were used to select literature to inform this review.

Populations
The relevant population of interest are individuals with obesity.

Interventions
The therapy being considered is gastric electrical stimulation.

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 gastric electrical stimulation as a treatment for obesity has varying lengths of follow up. While studies described below all reported at least one outcome of interest, longer follow-up was necessary to fully observe outcomes. Therefore, one 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.(12) 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=0.717).

Small case series and uncontrolled prospective trials (2002-2004) have reported positive outcomes for weight loss and maintenance of weight loss along with minimal complications.(13-18) 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.

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. GES may be an option for patients with debilitating gastroparesis that 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 GES, 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 SHAPE trial did not show significant improvement in weight loss using GES compared with sham stimulation. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Supplemental Information

CLINICAL INPUT RECEIVED 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.

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, BCBSA received input 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 use of GES in diabetic and idiopathic gastroparesis and about the need for RCTs. There was strong agreement that GES is investigational in the treatment of obesity.

PRACTICE GUIDELINES AND POSITION STATEMENTS

National Institute for Health and Care Excellence

The National Institute for Health and Care Excellence (2014) issued guidance on gastroelectrical stimulation for gastroparesis.(17) 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.

American College of Gastroenterology

The American College of Gastroenterology (2022) published practice guideline 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)."

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 in Table 3.

Table 3. 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 2024

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

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.

(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 & Medicare 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

1. Levinthal DJ, Bielefeldt K. Systematic review and meta-analysis: Gastric electrical stimulation for gastroparesis. Auton Neurosci. Jan 2017;202:45-55. PMID 27085627
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11. 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
12. Shikora SA, Bergenstal R, Bessler M, et al. Implantable gastric stimulation for the treatment of clinically severe obesity: results of the SHAPE trial. *Surg Obes Relat Dis.* Jan-Feb 2009;5(1):31-37. PMID 19071066
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16. De Luca M, Segato G, Busetto L, et al. Progress in implantable gastric stimulation: summary of results of the European multi-center study. *Obes Surg.* Sep 2004;14 Suppl 1:S33-39. PMID 15479588
17. Favretti F, De Luca M, Segato G, et al. Treatment of morbid obesity with the Transcend Implantable Gastric Stimulator (IGS): a prospective survey. *Obes Surg.* May 2004;14(5):666-670. PMID 15186636
18. Shikora SA. Implantable gastric stimulation for the treatment of severe obesity. Obes Surg. Apr 2004;14(4):545-548. PMID 15130236
19. National Institute of Health and Care Excellence. IPG489 Gastroelectrical stimulation for gastroparesis 2014; https://www.nice.org.uk/guidance/ipg489. Accessed May 29, 2024.

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The articles reviewed in this research include those obtained in an Internet based literature search for relevant medical references through 5/29/24, 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

Next Review Date: 3rd Qtr, 2025

BLUE CARE NETWORK BENEFIT COVERAGE
POLICY: GASTRIC ELECTRICAL STIMULATION

I. 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.

II. Administrative Guidelines:

- The member's contract must be active at the time the service is rendered.
- Coverage is based on each member's certificate and is not guaranteed. Please consult the individual member's certificate for details. Additional information regarding coverage or benefits may also be obtained through customer or provider inquiry services at BCN.
- The service must be authorized by the member's PCP except for Self-Referral Option (SRO) members seeking Tier 2 coverage.
- Services must be performed by a BCN-contracted provider, if available, except for Self-Referral Option (SRO) members seeking Tier 2 coverage.
- Payment is based on BCN payment rules, individual certificate and certificate riders.
- Appropriate copayments will apply. Refer to certificate and applicable riders for detailed information.
- CPT - HCPCS codes are used for descriptive purposes only and are not a guarantee of coverage.