



# BlueCross BlueShield of Vermont

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## Corporate Medical Policy Gastric Electrical Stimulation

**File name:** Gastric Electrical Stimulation

**File code:** UM.NS.06

**Origination:** 2007

**Last Review:** 05/2014

**Next Review:** 05/2015

**Effective Date:** 10/2014

### Document Precedence

Blue Cross and Blue Shield of Vermont (BCBSVT) Medical Policies are developed to provide clinical guidance and are based on research of current medical literature and review of common medical practices in the treatment and diagnosis of disease. The applicable group/individual contract and member certificate language determines benefits that are in effect at the time of service. Since medical practices and knowledge are constantly evolving, BCBSVT reserves the right to review and revise its medical policies periodically. To the extent that there may be any conflict between medical policy and contract language, the member's contract language takes precedence.

### Medical Policy

#### Description

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

#### Background

Currently, only one gastric electrical stimulator has received approval from the U.S. Food and Drug Administration (FDA) (see note below), the Gastric Electrical Stimulator (GES) system (now called Enterra™ Therapy System), manufactured by Medtronic. 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 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 sec alternating with an “off” time of 5.0 sec.

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’s disease, and psychological pathologic conditions. Treatment of gastroparesis includes prokinetic agents, such as metoclopramide, and antiemetic agents, such as metoclopramide, granisetron, or ondansetron. Severe cases may require enteral or total parenteral nutrition.

Gastric electrical stimulation has also been investigated as a treatment of obesity as a technique to increase a feeling of satiety with subsequent reduced food intake and weight loss. The exact mechanisms resulting in changes in eating behavior are uncertain but may be related to neuro-hormonal modulation and/or stomach muscle stimulation. There are no gastric electrical stimulation devices approved by the FDA for the treatment of obesity. The Transcend® Implantable Gastric Stimulation device, manufactured by Transneuronix Corporation and acquired by Medtronic in 2005, is currently available in Europe for treatment of obesity. Medtronic announced in December 2005 that the preliminary results of the Screened Health Assessment and Pacer Evaluation, or SHAPE trial, which was initiated by Transneuronix using the Transcend device, “did not meet the efficacy endpoint of a difference in mean excess weight loss at one year.”

**Note:**

It should be noted that the GES system received FDA approval through a humanitarian device exemption (HDE). This regulatory category was established in 1996 and only applies to devices intended to benefit fewer than 4,000 patients. The approval process is similar to that of a premarket approval application (PMA) but is exempt from the effectiveness requirements of a PMA. Thus the application is not required to include results of scientifically valid clinical investigations but must contain sufficient information for the FDA to determine that the device does not pose unreasonable or significant risk of illness or injury. A humanitarian use device may only be used in facilities that have an institutional review board (IRB) to supervise clinical testing of the device.

**Policy**

Gastric electrical stimulation is considered **investigational** for the treatment of gastroparesis of diabetic, idiopathic, or post-surgical etiology.

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

## Administrative and Contractual Guidance

### Benefit Determination Guidance

Prior approval is required and benefits are subject to all terms, limitations and conditions of the subscriber contract.

An approved referral authorization for members of the New England Health Plan (NEHP) is required. A prior approval for Access Blue New England (ABNE) members is required. NEHP/ABNE members may have different benefits for services listed in this policy. To confirm benefits, please contact the customer service department at the member's health plan.

Benefits for FEP members may vary. Please consult the FEP Service Plan Brochure.

Coverage varies according to the member's group or individual contract. Not all groups are required to follow the Vermont legislative mandates. Member Contract language takes precedence over medical policy when there is a conflict.

If the member receives benefits through a self-funded (ASO) group, benefits may vary or not apply. To verify benefit information, please refer to the member's plan documents or contact the customer service department.

### Billing and Coding/Physician Documentation Information

Click the links below for attachments, coding tables & instructions.

[Attachment I- CPT Code List & Instructions](#)

### Audit Information

BCBSVT reserves the right to conduct audits on any provider and/or facility to ensure compliance with the guidelines stated in the medical policy. If an audit identifies instances of non-compliance with this medical policy, BCBSVT reserves the right to recoup all non-compliant payments.

### Policy Implementation/Update information

02/2007	New Policy
03/2008	Policy reformatted to match BCBSA Medical Policy format and reviewed by CAC.
07/2009	Medical necessity criteria clarified and aligned with Anthem Blue Cross (New Hampshire) 0162T Code deleted and removed from Appendix.
8/2011	Policy presented in new format. References expanded and updated. Added HCPCS coding. Revised ICD-9 codes. Deleted unlisted procedure CPT code. Added ICD-10 Diagnosis codes where applicable. Codes reviewed and approved by Medical/clinical coder SAR 9/26/11.
2/2014	ICD-10 remediated. New standard language added (document precedence, Audit information, Group and ASO language).
5/2014	Updated policy effective: 10/2014. Adopted BCBSA policy 7.01.73.

	Investigational for all indications. "C" code for neurostimulators kept in BCBSVT policy since they correlate with primary procedure. Category III codes 0155T-0158T removed- deleted in 2012.
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## Rationale

This policy was originally created in December 2000 and was regularly updated with searches of the MEDLINE database. The most recent literature search was performed through June 18, 2013. The following is a summary of the key findings to date.

### Gastroparesis

The evidence on gastric electrical stimulation (GES) for gastroparesis consists of 2 small randomized crossover trials, and numerous case series. The case series include several that report on medium and/or long-term use (greater than 1 year of follow-up) of the device.

#### *Systematic reviews*

In a 2012 systematic review and meta-analysis, Chu and colleagues (1) evaluated 10 studies on GES for the treatment of gastroparesis. Included in the meta-analysis were 2 randomized controlled trials (RCT) by Abell (2) and McCallum (3), both et al. and 8 observational studies, totaling 601 patients who received GES for more than 1 month. The treatment arms of the RCTs were combined with the single-arm case series to give summary estimates of treatment effect. This review did not attempt to evaluate the RCTs separately from the case series and, therefore, did not attempt to make conclusions on the efficacy of GES compared to a control group.

The meta-analysis found gastric electrical stimulation significantly improved scores for total symptom severity, nausea severity, and vomiting severity. Gastric emptying times at 2 and 4 hours also significantly improved. In the sub-analysis of 197 patients with diabetic gastroparesis, total symptom severity scores and gastric emptying at 2 and 4 hours significantly improved. In the sub-analysis of 65 patients with idiopathic gastroparesis, total symptom severity scores and gastric emptying at 4 hours significantly improved but not at 2 hours. In the sub-analysis of 40 patients with post-surgical gastroparesis, total symptom severity scores and gastric emptying at 2 hours significantly improved but not at 4 hours. A sub-analysis of nausea and vomiting severity scores was not presented. Infection (3.87%) was the most common complication followed by device migration (2.69%) and pain at the site of implant (0.67%). Other infrequent complications (1.18%) included peptic ulcer disease, electrode penetration of the stomach lumen, erosion of the skin after abdominal wall trauma, and implant wire-related small bowel obstruction. While this meta-analysis found GES provided significant benefit in gastroparesis treatment, interpretation of results must be made with caution, since the majority of studies analyzed were low-quality observational studies. Only 2 studies had control groups, and the control groups of these RCTs were not included in the combined analysis.

#### *Randomized, controlled trials*

The data presented to the U.S. Food and Drug Administration (FDA) documenting the “probable benefit” of the GES system was based on a multicenter, double-blinded crossover study, the Worldwide Anti-Vomiting Electrical Stimulation Study (WAVESS). (4) The study included 33 patients with intractable idiopathic or diabetic gastroparesis. The primary endpoint of the study 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. The baseline vomiting frequency was 47 episodes per month, which significantly declined in both on and off groups to 23 to 29 episodes, respectively. However, no significant differences were found in the number of vomiting episodes between the 2 groups, suggesting a placebo effect.

The final results of the WAVESS study were reported in 2003, which allows further review of the data. (2) When looking individually at those with idiopathic gastroparesis, there was a similar drop in vomiting frequency compared to baseline regardless of whether the device was turned on or off, suggesting a placebo effect. In contrast, in those with diabetic gastroparesis, compared to baseline, there was a small drop in vomiting frequency with the device turned off, compared to a larger drop in vomiting frequency with the device turned on. In the second open-label phase of the trial, all patients had their stimulators turned on for the remainder of the 6 to 12 months’ follow-up. During this period, the vomiting frequency declined in both the idiopathic and diabetic subgroups. The cause of this continuing decline is uncertain, related to either a placebo effect or some sort of long-term effect of gastric stimulation.

McCallum and colleagues performed a multicenter prospective study to evaluate GES (Enterra therapy) in patients with chronic intractable nausea and vomiting from diabetic gastroparesis (DGP). (3) In this study, 55 patients with refractory DGP (5.9 years of DGP) were given implants of the Enterra system. After surgery, all patients had the stimulator turned on for 6 weeks and then were randomly assigned 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 difference in WVF between patients who had the device turned on or off during the 3-month cross-over period. At 1 year, the WVF of all patients was significantly lower than baseline values (median reduction, 68%;  $p$  less than 0.001). One of the patients had the device removed due to infection; 2 patients required surgical intervention due to lead-related problems.

**Conclusions.** Two small, crossover RCTs have been performed on GES for gastroparesis. In addition to being small in numbers, these RCTs have methodologic limitations including the use of a crossover design that may limit the ability to maintain successful blinding. In each RCT, patients in both of the treatment groups improved, but it is not possible to determine whether the improvement was due to GES treatment or due to a placebo effect.

### *Case series*

Anand and colleagues reported on 214 consecutive drug-refractory patients with the symptoms of gastroparesis (146 idiopathic, 45 diabetic, 23 after surgery) who consented to participate in a variety of clinical research and clinical protocols at 3 centers from January 1992 through January 2005, resulting in 156 patients implanted with a GES device and 58 patients as controls. (5) At last follow-up (median 4 years), most patients who received implants (135 of 156) were alive with intact devices, significantly reduced gastrointestinal symptoms, and improved health-related quality of life, with evidence of improved gastric emptying. Also, 90% of the patients had a response in at least 1 of 3 main symptoms. Most patients who were explanted, usually for pocket infections, were later re-implanted successfully.

In a case series of 12 patients receiving a gastric stimulation device, Abell and colleagues reported rapid improvement in nutritional parameters (e.g., body mass index, serum albumin). (6) Forster and colleagues reported on their experience at a single institution among 55 patients with gastroparesis, as documented by gastric retention. (7) While the total symptom score improved, gastric emptying did not change. The authors reported significant improvements in upper gastrointestinal symptoms, health-related quality of life, nutritional status, glucose control, and hospitalizations at 6 and 12 months in a retrospective review of 48 adult patients with diabetes who received a gastric electrical stimulation implant. (6) The review also noted that gastric emptying was not significantly faster. Similarly, van der Voort and colleagues reported that 17 patients with diabetic gastroparesis experienced a decrease in nausea and vomiting and an improvement in glucose control in a prospective case series examining the 12-month outcomes. (8)

Several trials were identified that evaluated the use of a temporary gastric stimulator. Temporary stimulators are intended to be used to determine whether or not an individual patient will respond to GES prior to undertaking a permanent implant. In 2013, Lahr and colleagues reported significant improvement during temporary GES (placement for at least 4 days) in 95 drug-refractory patients with symptoms of gastroparesis (abdominal pain, bloating, early satiety, nausea, vomiting). (9) For the entire group of patients, abdominal pain decreased from a baseline of 2.95 on a 0-4 modified Likert scale to 1.12 after temporary GES ( $p<0.001$ ). In a sub-set of patients reporting severe pain at baseline ( $n=68$ ), as defined by a score of 3-4 on the pain scale, mean pain scores decreased from 3.62 to 1.29 ( $p<0.001$ ). There were also reductions of similar magnitude on symptom scores for early satiety, abdominal distension, nausea, and vomiting. (9)

Abell et al. (10) performed a trial of temporary GES in 58 patients with 1 of 3 etiologies (idiopathic, diabetic, postsurgical). A temporary device was placed in all patients with the device turned on or off for 4 consecutive days, followed by cross-over to the other group for an additional 4-day period. The frequency of vomiting decreased in both groups. At day 3, the decrease in vomiting was significantly greater for the GES group; however, by day 8, the differences between groups were no longer significant.

Andersson et al. (11) tested a temporary GES in 27 patients with drug-refractory nausea/vomiting. Fourteen patients were treated with temporary GES in open-label fashion, and 13 had a randomized, cross-over trial in which the device was turned on

for 12-14 days and off for 12-14 days. These authors reported that the majority of patients (22/27) improved following GES placement. Of the 13 patients in the randomized cross-over phase, 6 had improvement in symptoms during the on period and 7 did not. Of the 7 patients who did not improve during the on period, there was improvement with an increased intensity of stimulation.

Elfvin et al. (12) treated 3 children with intractable vomiting who were younger than 3 years-old with a temporary GES. There were no adverse events of GES placement. All 3 children responded to the temporary GES and were implanted with a permanent device. Following permanent placement, all 3 children reported at least a 50% reduction in vomiting episodes. Significant improvement after GES placement in symptoms of nausea and vomiting were also reported in another series of 16 children with functional dyspepsia and gastroparesis who failed medical therapy. (13)

The durability of GES treatment was evaluated in several publications. Lin and colleagues reported on outcomes beyond 3 years in patients receiving GES for gastroparesis. (14) Of 55 patients, 10 died of non-pacemaker-related complications, 6 had the devices removed, and 2 could not be reached. In the remaining 37 patients, symptoms, hospital days, and the use of medications had sustained reductions (from baseline) beyond 3 years. Mason and colleagues reported on the 20-month follow-up of 27 of 29 patients referred for gastrectomy who instead received GES for refractory gastroparesis. (15) Three patients required additional procedures due to poor outcomes. Nutritional support was discontinued in the 19 patients who were dependent on supplemental feeding prior to the procedure. Gastric emptying rates improved. While these results are encouraging, given the findings of the WAVESS study, randomized trials are needed to determine the efficacy of GES in gastroparesis.

McCallum et al. reported on long-term follow-up for 188 patients who received a GES and had at least 1 year of follow-up visits. (16) This sample was drawn from a total of 221 patients treated with a GES system between 1 and 11 years prior to the study. The authors report that symptoms, hospitalizations, and medication use all improved over the time period of the study. The percent of patients with at least 50% improvement in symptoms was 58% for diabetic patients, 53% for postsurgical gastroparesis, and 48% for idiopathic disease. A total of 13 patients (7%) had their device removed due to infection.

GES placement using minimally invasive surgical approaches has also been evaluated in several publications. Laparoscopy has been reported in at least two studies as a feasible approach in placement of GES for patients with medically refractory diabetic or idiopathic gastroparesis. (17, 18)

**Conclusions.** Numerous case series and uncontrolled studies on GES have been published. These studies generally report improvements in symptoms following treatment. However, this evidence is insufficient to draw conclusions because of the lack of control groups and the possibility that improvement is due to a placebo effect and/or other non-specific factors.

## Obesity

There has only been 1 RCT published on GES for the treatment of obesity: the SHAPE trial. In 2009, Shikora and colleagues reported on a randomized, controlled, double-blind study to evaluate GES for the treatment of obesity. (19) All 190 patients participating in the study 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 diet by 500-kcal/day. At 12 months follow-up, there was no difference in excess weight loss between the treatment group (weight loss of 11.8% +/- 17.6%) and the control group (weight loss of 11.7% +/- 16.9%) using intention-to-treat analysis (p=0.717).

Small case series and uncontrolled prospective trials have reported positive outcomes in weight loss and maintenance of weight loss along with minimal complications. (20-25) However, interpretation of these uncontrolled studies is limited. In conclusion, given the available evidence including the results of the SHAPE RCT, GES for the treatment of obesity is considered investigational.

### **Ongoing Clinical Trials**

A search of online site ClinicalTrials.gov identified one randomized double-blind cross-over study of gastric electrical stimulation (NCT00903799). In this study, health and healthcare utilization outcomes will be evaluated in 220 patients with diabetes, idiopathic or post-surgical related refractory nausea and vomiting. This study is currently recruiting participants and This study is expected to be completed in October 2013. In addition, a manufacturer-sponsored feasibility study is being undertaken to provide safety data on a new implantable GES system for the treatment of obesity; 30 adult patients will be enrolled in this study with the estimated completion date of September 2016 (NCT01823705).

### **Clinical Input Received through Physician Specialty Societies and Academic Medical Centers**

In response to requests, input was received through no physician specialty societies and 4 academic medical centers (5 reviewers) while this policy was under review for May 2009. 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. There was strong agreement among reviewers about the limited data for use of GES in diabetic and idiopathic gastroparesis and about the need for randomized controlled studies. There was strong agreement that GES is investigational in the treatment of obesity.

### **Summary**

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

The evidence on the efficacy of gastric electrical stimulation to treat gastroparesis is inadequate to permit scientific conclusions. Only two small randomized studies have been published on the treatment of gastroparesis. In one randomized study, only 33 patients recruited from 11 centers in the United States were included. There was no statistically significant improvement in symptoms for the entire study group compared to placebo, but positive results were reported for the subgroup of 17 patients with diabetic gastroparesis. In the other randomized study of 55 patients, while weekly vomiting frequency was significantly lower than baseline values at one-year follow-up, there was no difference in weekly vomiting frequency between patients who had the device turned on or off during the 3-month cross-over period. The case series report improvements in symptoms, nutritional parameters, and quality of life. However, the lack of a control group precludes the conclusion that these changes are due to treatment with gastric electrical stimulation, given the variable natural history of gastroparesis, and the expected placebo effect. In conclusion, gastric electrical stimulation for the treatment of gastroparesis of diabetic, idiopathic, or post-surgical etiologies is considered investigational.

There has only been one published randomized study on gastric electrical stimulation for the treatment of obesity (the SHAPE trial), which did not show any improvement in weight loss with gastric electrical stimulation. Case series publications are limited and insufficient to draw conclusions on health outcomes. Given the results of the SHAPE trial, gastric electrical stimulation for the treatment of obesity is considered investigational.

### **Practice Guidelines and Position Statements**

The American College of Gastroenterology published a clinical practice guideline on management of gastroparesis in 2013. (26) The recommendations for this guideline were based on review of the evidence base through 2011. The evidence on GES consisted of the two randomized crossover trials and the case series, as described above. The recommendation for GES was that “GES may be considered for compassionate treatment in patients with refractory symptoms, particularly nausea and vomiting. Symptom severity and gastric emptying have been shown to improve in patients with DG [diabetic gastroparesis], but not in patients with IG [idiopathic gastroparesis] or PSG [postsurgical gastroparesis]. [Conditional recommendation (there is uncertainty about trade-offs), moderate level of evidence (further research would be likely to have an impact on the confidence in the estimate of effect).]” (26)

The National Institute for Health and Care Clinical Excellence (NICE) issued guidance on gastroelectrical stimulation for gastroparesis in 2004. (27) This guidance indicates there is insufficient evidence to support gastroelectrical stimulation for gastroparesis outside of audit or research purposes. This guidance was considered for reassessment in October 2009, and it was concluded that NICE would not be updating the guidance at that stage.

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Approved by BCBSVT Medical Directors

Date Approved

Robert Wheeler MD  
Chief Medical Officer

**Attachment I**  
**CPT Code List & Instructions**

Code Type	Number	Description	Policy Instructions
<b>The following codes will be denied as Not Medically Necessary, Contract Exclusions or Investigational</b>			
CPT	43647	Laparoscopy, surgical; implantation or replacement of gastric neurostimulator electrodes, antrum	Investigational

CPT	43648	Laparoscopy, surgical, revision or removal of gastric neurostimulator electrodes, antrum	Investigational
CPT	43881	Implantation or replacement of gastric neurostimulator electrodes, antrum, open	Investigational
CPT	43882	Revision or removal of gastric neurostimulator electrodes, antrum, open	Investigational
CPT	64590	Insertion or replacement of peripheral or gastric neurostimulator pulse generator or receiver, direct or inductive coupling	Investigational
CPT	64595	Revision or removal of peripheral or gastric neurostimulator pulse generator or receiver	Investigational
CPT	95980	Electronic analysis of implanted neurostimulator pulse generator	Investigational
CPT	95981	Subsequent, without reprogramming	Investigational
CPT	95982	Subsequent, with reprogramming	Investigational
HCPCS	C1767	Generator, neurostimulator, implantable, non-rechargeable	Investigational
HCPCS	C1778	Lead, neurostimulator, implantable	Investigational
HCPCS	C1820	Generator, neurostimulator (implantable), with rechargeable battery and charging system	Investigational

HCPCS	L8680	Implantable neurostimulator electrode (with any number of contact points), each	Investigational
HCPCS	L8685	Implantable neurostimulator pulse generator, single array, rechargeable, includes extension	Investigational
HCPCS	L8686	Implantable neurostimulator pulse generator, single array, non-rechargeable, includes extension	Investigational
HCPCS	L8687	Implantable neurostimulator pulse generator dual array, rechargeable, includes extension	Investigational
HCPCS	L8688	Implantable neurostimulator pulse generator, dual array, non-rechargeable, includes extension	Investigational
Type of Service	Medicine, Surgical		
Place of Service	Inpatient, Outpatient		