Corporate Medical Policy
Gastric Electrical Stimulation

File name: Gastric Electrical Stimulation
File code: UM.NS.06
Origination: 2007
Last Review: 02/2017
Next Review: 02/2018
Effective Date: 05/01/2017

Description/Summary

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 post-surgical etiology. GES has also been investigated as a treatment of obesity. The device may be referred to as a gastric pacemaker.

Policy

Coding Information
Click the links below for attachments, coding tables & instructions.
Attachment I- CPT Code List & Instructions

When a service is considered investigational

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.

Background

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 that are implanted during laparoscopy or open laparotomy (see Regulatory Status section).
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. 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.

For individuals who have gastroparesis who receive GES, the evidence includes randomized controlled trials (RCTs) and systematic reviews. Relevant outcomes are symptoms and treatment-related morbidity. Five crossover RCTs have been published. A 2017 meta-analysis of these 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. The evidence is insufficient to determine the effects of the technology on health outcomes.

GES 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.

For individuals who have obesity who receive GES, the evidence includes 1 published randomized study. Relevant outcomes are change in disease status and treatment-related morbidity. The published RCT (the SHAPE trial) did not show significant improvement in weight loss with GES compared with sham stimulation. The evidence is insufficient to determine the effects of the technology on health outcome.

There are no GES devices approved by the U.S. Food and Drug Administration for the treatment of obesity. The Transcend® Implantable Gastric Stimulation device, acquired by Medtronic in 2005, is available in Europe for treatment of obesity.

**Regulatory Status**

In 2000, the Gastric Electrical Stimulator (GES) system (now called Enterra™ Therapy System; Medtronic, Minneapolis, MN) was approved by the U.S. Food and Drug Administration (FDA) through the humanitarian device exemption process ((HDE Approval H990014). 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 second alternating with an “off” time of 5.0 second.

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 December 22, 2016. The following is a summary of the key findings to date.

**Gastric Electrical Stimulation for Gastroparesis**

**Systematic reviews**

Several systematic reviews of studies on GES for gastroparesis have been published, the most recent and comprehensive of which was a systematic review and meta-analysis published by Levinthal et al (2017). To be included in the review, studies needed to include adults with established gastroparesis, report patient symptom scores and administer treatment for at least 1 week. A total of 5 randomized controlled trials (RCTs) and 13 non-RCTs meeting criteria were identified. Pooled analysis of data from the 5 RCTs (n=185 patients) 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). In addition, 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 pooled analysis of 13 open-label single-arm studies and data from open-label extensions of 3 RCTs, the mean total symptom severity score decreased 2.68 (95% CI, 2.04 to 3.32) at follow-up compared with a mean baseline score of 6.85 (95% CI, 6.28 to 7.42). 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**

Representative crossover RCTs are described next. In 2003, Abell et al reported findings of the Worldwide Anti-Vomiting Electrical Stimulation Study (WAVESS). This double-blind crossover study, initially described in FDA materials, included 33 patients with intractable idiopathic or diabetic gastroparesis. The primary end point 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 to 29 episodes, respectively. However, no statistically 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.

In 2010, McCallum et al reported on a crossover RCT evaluating GES (Enterra therapy) in patients with chronic intractable nausea and vomiting from diabetic gastroparesis (DGP). 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 crossover 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 of the patients had the device removed due to infection; 2 patients required surgical intervention due to lead-related problems.

In 2013, McCallum et al evaluated GES (Enterra system) in patients with chronic vomiting due to idiopathic gastroparesis in a randomized, double-blind crossover trial. In this study, 32 patients with nausea and vomiting associated with idiopathic gastroparesis, which was 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 demonstrated improvements in their WVF, demonstrating a median reduction of 61.2% compared with baseline (17.3 episodes/week at baseline vs 5.5 episodes/week at 6 week postimplant, p<0.001). During the on-off crossover phase, subjects demonstrated no significant differences between the on and off phase in the study’s primary end point, median WVF (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 WVF compared with baseline (17.3 episodes/week at baseline vs 2 episodes/week at 12-month follow-up, p<0.001). Two subjects required surgical intervention for lead migration/dislodgement or neurostimulator migration.

Section Summary: Gastric Electrical Stimulation for Gastroparesis

Five crossover RCTs have been published. A 2017 meta-analysis of these 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 not a significant difference in the on versus off position in symptom severity or nausea severity scores.

**Gastric Electrical Stimulation For Obesity**

There has only been 1 RCT published on GES for the treatment of obesity: the SHAPE trial. In 2009, Shikora et al reported on a randomized controlled, double-blind study to evaluate GES for the treatment of obesity. 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/d. At 12-month follow-up, there was no statistically significant difference in excess weight loss between the treatment group (weight loss, 11.8%±17.6%) and the control group (weight loss, 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. However, interpretation of these uncontrolled studies is limited.

**Summary of Evidence**

For individuals who have gastroparesis who receive GES, the evidence includes randomized controlled trials (RCTs) and systematic reviews. Relevant outcomes are symptoms and treatment-related morbidity. Five crossover RCTs have been published. A 2017 meta-analysis of these 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. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have obesity who receive GES, the evidence includes 1 published randomized study. Relevant outcomes are change in disease status and treatment-related morbidity. The published RCT (the SHAPE trial) did not show significant improvement in weight loss with GES compared with sham stimulation. The evidence is insufficient to determine the effects of the technology on health outcomes.

**Ongoing Clinical Trials**

A search of ClinicalTrials.gov in Jan 2017 did not identify any ongoing or unpublished trials that would likely influence this review.

**Clinical Input Received through 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
In response to requests, input was received through 1 specialty society (2 reviewers) and 4 academic centers while this policy was under review in 2015. 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 (eg, diabetic gastroparesis, idiopathic gastroparesis, gastroparesis of postsurgical etiology). The reviewers were not asked about GES for treatment of obesity.

2009 Input
In response to requests, input was received through 4 academic medical centers (5 reviewers) while this policy was under review in 2009. 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
In 2014, the National Institute for Health and Care Excellence issued guidance on gastroelectrical stimulation for gastroparesis that 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 During the consent process, 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.
1.4 Further publications providing data about the effects of the procedure on symptoms in the long term and on device durability would be useful.”

American College of Gastroenterology
The American College of Gastroenterology published a clinical practice guideline on management of gastroparesis in 2013. The recommendation was that “GES [gastric electrical stimulation] 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]."
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).]

Reference Resources


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, or employer’s benefit plan if an ASO group, 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/employer benefit plan language, the member’s contract/employer benefit plan language takes precedence.

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.

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.

Federal Employee Program (FEP): Members may have different benefits that apply. For further information please contact FEP customer service or refer to the FEP Service Benefit Plan Brochure. It is important to verify the member’s benefits prior to providing the service to determine if benefits are available or if there is a specific exclusion in the member’s benefit.
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 an Administrative Services Only (ASO) group, benefits may vary or not apply. To verify benefit information, please refer to the member’s employer benefit plan documents or contact the customer service department. Language in the employer benefit plan documents takes precedence over medical policy when there is a conflict.

**Policy Implementation/Update information**

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<th>Date</th>
<th>Description</th>
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<tr>
<td>02/2007</td>
<td>New Policy</td>
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<tr>
<td>03/2008</td>
<td>Policy reformatted to match BCBSA Medical Policy format and reviewed by CAC.</td>
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<tr>
<td>07/2009</td>
<td>Medical necessity criteria clarified and aligned with Anthem Blue Cross (New Hampshire) 0162T Code deleted and removed from Appendix.</td>
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<tr>
<td>2/2017</td>
<td>Rearranged policy to align with Association as this is an adopted policy. No change to position statements. Updated references. No changes to coding updated coding table to reflect all codes require PA.</td>
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**Approved by BCBSVT Medical Directors**

Gabrielle Bercy-Roberson, MD, MPH  
Senior Medical Director  
Chair, Health Policy Committee

Joshua Plavin, MD, MPH  
Chief Medical Officer
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<tr>
<th>Code Type</th>
<th>Number</th>
<th>Description</th>
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<tr>
<td>CPT</td>
<td>43647</td>
<td>Laparoscopy, surgical; implantation or replacement of gastric neurostimulator electrodes, antrum</td>
<td>Requires Prior Approval</td>
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<td>CPT</td>
<td>43648</td>
<td>Laparoscopy, surgical, revision or removal of gastric neurostimulator electrodes, antrum</td>
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<td>CPT</td>
<td>43881</td>
<td>Implantation or replacement of gastric neurostimulator electrodes, antrum</td>
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<td>CPT</td>
<td>43882</td>
<td>Revision or removal of gastric neurostimulator electrodes, antrum, open</td>
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<td>CPT</td>
<td>64590</td>
<td>Insertion or replacement of peripheral or gastric neurostimulator pulse generator or receiver, direct or inductive coupling</td>
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<td>CPT</td>
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<td>Revision or removal of peripheral or gastric neurostimulator pulse generator or receiver</td>
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<td>Electronic analysis of implanted neurostimulator pulse generator</td>
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<td>CPT</td>
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<td>Subsequent, without reprogramming</td>
<td>Requires Prior Approval</td>
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<td>CPT</td>
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<td>Subsequent, with reprogramming</td>
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<td>HCPCS</td>
<td>C1767</td>
<td>Generator, neurostimulator, implantable, non-rechargeable</td>
<td>Requires Prior Approval</td>
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The following codes will be denied Investigational.
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<th>HCPCS</th>
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<th>Description</th>
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<td>C1778</td>
<td>Lead, neurostimulator, implantable</td>
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<td>C1820</td>
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<td>L8680</td>
<td>Implantable neurostimulator electrode (with any number of contact points), each</td>
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<td>Requires Prior Approval</td>
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