Title: Gastric Electrical Stimulation

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## DESCRIPTION

<table>
<thead>
<tr>
<th>Populations</th>
<th>Interventions</th>
<th>Comparators</th>
<th>Outcomes</th>
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<tr>
<td>Individuals:</td>
<td>Interventions of interest are:</td>
<td>Comparators of interest are:</td>
<td>Relevant outcomes include:</td>
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<tr>
<td>• With gastroparesis</td>
<td>• Gastric electrical stimulation</td>
<td>• Conservative management</td>
<td>• Symptoms</td>
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<td></td>
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<td>• Medication</td>
<td>• Treatment-related morbidity</td>
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<td>• Enteral or total parenteral nutrition</td>
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<td>Individuals:</td>
<td>Interventions of interest are:</td>
<td>Comparators of interest are:</td>
<td>Relevant outcomes include:</td>
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<tr>
<td>• With obesity</td>
<td>• Gastric electrical stimulation</td>
<td>• Conservative management</td>
<td>• Change in disease severity</td>
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<td>• Medication</td>
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<td>• Bariatric surgery</td>
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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.

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's 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.

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. 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, manufactured by Transneuronix 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."

**Regulatory Status**
Currently, only the Gastric Electrical Stimulator (GES) system (now called Enterra™ Therapy System Medtronic, Minneapolis, MN) has been approved by the U.S. Food and Drug Administration (FDA; see note below). 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.

Note: In March 2000, the GES system was approved by FDA through a humanitarian device exemption (HDE Approval H990014). This regulatory category was established in 1996 and only applies to devices intended to benefit fewer than 4000 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 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 to supervise clinical testing of the device.

**POLICY**

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

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

**RATIONALE**

The most recent literature review was performed through November 10, 2015. The following is a summary of the key findings to date.

**Permanent Gastric Electrical Stimulation for Gastroparesis**

The evidence on gastric electrical stimulation (GES) for gastroparesis consists of 3 small randomized crossover trials and numerous case series. The case series include several that report on medium and/or long-term use (>1 year of follow-up) of the device.

**Systematic Reviews**

In a 2012 systematic review and meta-analysis, Chu et al\(^1\) evaluated 10 studies on GES for the treatment of gastroparesis. Included in the meta-analysis were 2 randomized controlled trials (RCTs) by Abell et al\(^2\) and McCallum et al\(^3\) 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 with a control group.

The meta-analysis found GES 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 subanalysis of 197 patients with diabetic gastroparesis, total symptom severity scores and gastric emptying at 2 and 4 hours significantly improved. In the subanalysis 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 subanalysis of 40 patients with postsurgical gastroparesis, total symptom severity scores and gastric emptying at 2 hours significantly improved but not at 4 hours. A subanalysis 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, because most 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.

A 2015 systematic review by Lal et al identified 21 studies with at least 10 participants who were treated with GES for gastroparesis and followed for at least 6 months. Most studies were observational. Outcome measures varied and the authors did not pool study findings. The authors reported that most studies found a reduction in symptom severity, but changes in gastric emptying were variable and generally did not correlate with symptom improvement.

Randomized Controlled Trials
The data presented to the U.S. Food and Drug Administration 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). The study included 33 patients with intractable idiopathic or diabetic gastroparesis. The primary end point 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. Among those with idiopathic gastroparesis, there was a similar drop in vomiting frequency compared with baseline regardless of whether the device was turned on or off, suggesting a placebo effect. In contrast, in those with diabetic gastroparesis, compared with baseline, there was a small drop in vomiting frequency with the device turned off, compared with 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 month 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 et al performed a multicenter prospective study to evaluate 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 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 a later study, 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: Systematic Reviews and RCTs on Gastroparesis
Three 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 none of the studies demonstrated differences between groups during the crossover phases. Therefore, it is not possible to determine whether the improvement was due to GES treatment or due to a placebo effect.

Uncontrolled Studies
A number of series have been published, many of which had small sample sizes. Representative large, prospective studies with longer term follow-up are described next:

In 2015, Brody et al reported on 79 patients who were refractory to nonoperative gastroparesis treatments who underwent GES implantation. After 1 year, 16 of 52 patients with available data (30.8%) had at least a 25% reduction in pain, and 23 of 52 (44.2%) had at least a 25% reduction in functional symptom severity, compared with baseline. Eighteen patients had 4- to 8-year follow-up data. Compared with baseline, 6 of 18 (33.3%) reported at least a 25% in pain, and 12 (66.7%) reported at least a 25% in functional symptom severity. There was no 30-day mortality, but 11 patients (14%) died over the 10-year study period. None of the deaths was GES-related.
In 2011, McCallum et al reported on follow-up for 188 patients who received a GES and had at least 1 year of follow-up visits. This sample was drawn from a total of 221 patients treated with a GES system between 1 and 11 years before 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.

Anand et al reported in 2007 reported on 214 consecutive drug-refractory patients with the symptoms of gastroparesis (146 idiopathic, 45 diabetic, 23 postsurgery) 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. At last follow-up (median, 4 years), most patients who received implants (135/156) 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 successfully replanted.

GES placement using minimally invasive surgical approaches has also been evaluated in several publications. Laparoscopy has been reported in at least 2 studies as a feasible approach in placement of GES for patients with medically refractory diabetic or idiopathic gastroparesis.

Section Summary: Uncontrolled Studies on Gastroparesis
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 nonspecific factors.

Permanent GES 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 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.

Temporary GES
Several studies were identified that evaluated the use of a temporary gastric stimulator. Temporary stimulators are intended to be used to determine whether or not a patient will respond to GES before undertaking a permanent implant. Temporary stimulation involves the endoscopic placement of a mucosal electrode, which is subsequently connected to the GES pulse generator system, which is carried externally by the patient. Some of the studies were small case
series \textsuperscript{24,25}; findings of higher quality, crossover trials, in which patients serve as their own controls, are described next.

Abell et al \textsuperscript{26} 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 crossover 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 \textsuperscript{27} 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, crossover trial in which the device was turned on for 12 to 14 days and off for 12 to 14 days. These authors reported that most patients (22/27) improved following GES placement. Of the 13 patients in the randomized crossover 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.

**Ongoing and Unpublished Clinical Trials**

Some currently unpublished trials that might influence this review are listed in Table 1.

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<td>Feb 2016</td>
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<td>Escalating Temporary Gastric Electrical Stimulation for Severe Gastroparesis</td>
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NCT: national clinical trial.

**Summary of Evidence**

The evidence for the use of gastric electrical stimulation (GES) for treatment of patients with gastroparesis includes 3 small randomized studies. Relevant outcomes are symptoms and treatment-related morbidity. One randomized study included only 33 patients recruited from 11 centers in the United States. No statistically significant improvement in symptoms was reported for the entire study group compared with placebo, but positive results were reported for the subgroup of 17 patients with diabetic gastroparesis. In the second randomized study of 55 patients, weekly vomiting frequency was significantly lower than baseline values at 1-year follow-up, but there was no difference in weekly vomiting frequency between patients who had the device turned on or off during the 3-month crossover period. A third study did not demonstrate differences in weekly vomiting frequency between patients who had the device turned on or off.
during the 3-month crossover period. The evidence is insufficient to determine the effects of the technology on health outcomes.

The evidence for the use of GES for treatment of obesity includes 1 published randomized study (SHAPE trial). Relevant outcomes are change in disease severity (eg, weight loss) and treatment-related morbidity. This trial did not show any improvement in weight loss with GES compared with sham stimulation. The evidence is insufficient to determine the effects of the technology on health outcomes.

**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.

**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**

In 2014, the National Institute for Health and Care Excellence issued guidelines on gastroelectrical stimulation for gastroparesis that 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.
- 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.
- 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.
- Further publications providing data about the effects of the procedure on symptoms in the long term and on device durability would be useful.

The American College of Gastroenterology published a clinical practice guideline on management of gastroparesis in 2013. The recommendations for this guideline were based on review of the
evidence base through 2011. The evidence on GES consisted of the 2 randomized crossover trials and the case series, as previously described. 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).]” 29

**U.S. Preventive Services Task Force Recommendations**
Not applicable.

**CODING**
The following codes for treatment and procedures applicable to this policy are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement. 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.

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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

- There are CPT codes that are specific to insertion of the gastric stimulation device: 43647, 43648, 43881, 43882, 64590, 64595.
- There are also specific codes for electronic analysis and programming of gastric neurostimulator pulse generator: 95980, 95981, 95982.
- The CPT code book instructs that after January 1, 2012, laparoscopic procedures related to gastric stimulation electrodes for morbid obesity should be reported using code 43659 and laparotomy procedures related to gastric stimulation electrodes for morbid obesity should be reported using 43999.
- The insertion of the gastric neurostimulator pulse generator is coded with 64590 and revision or removal of the pulse generator is coded with 64595, regardless of the indication.
- The following HCPCS codes may be used: L8680, L8685, L8686, L8687, L8688.

**Diagnoses**
Experimental / Investigational for all diagnoses related to this medical policy.

**REVISES**
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<td>- HCPCS nomenclature updated: L8660</td>
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<td>- Updated Coding notations.</td>
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**REFERENCES**


