Medical Coverage Policy

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Gastric Pacing/Gastric Electrical Stimulation (GES)

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Overview

This Coverage Policy addresses gastric electrical stimulation (GES) for the treatment of intractable nausea and vomiting secondary to gastroparesis.

Coverage Policy

Permanent gastric electrical stimulation (GES) or gastric pacing (e.g., Enterra™ Therapy) is considered medically necessary when provided in accordance with the Humanitarian Device Exemption (HDE) specifications of the U.S. Food and Drug Administration (FDA) for intractable nausea and vomiting secondary to gastroparesis with failure, contraindication, or intolerance of pharmaceutical therapy.

Gastric electrical stimulation (GES) or gastric pacing for any other indication is considered experimental, investigational or unproven.

Temporary gastric electrical stimulation (GES) is considered experimental, investigational or unproven.

General Background

Gastric electrical stimulation (GES) delivers electrical stimuli to the musculature of the gastric wall by means of electrodes which are connected to a stimulator device. The intent is to restore effective gastric contractions. GES has been proposed for patients with gastroparesis who are refractory to medical treatment. There are two principal types of GES devices that are available: (1) low-frequency/high-energy GES with long pulse stimulation; and (2) high-frequency/low-energy GES with short pulse stimulation (Lal, et al., 2015; Bortolotti, 2011).

Low-frequency/high-energy GES with long pulse stimulation, also called gastric pacing, uses frequencies close to or above the normal gastric slow wave cycle to reset regular slow wave rhythm. This type of GES involves heavy batteries, is not suitable for implantation and has a variable effect on the symptoms of gastroparesis (Lal, et al., 2015).

High-frequency/low-energy GES with short pulse stimulation (e.g., Enterra™ Therapy) is a type of gastric neurostimulation or neuromodulation (Lal, et al., 2015; Bortolotti, 2011). The device is implanted in the body and delivers high-frequency electrical stimulation at four times the basal rate (12 cycles per minute [cpm]) to the stomach. It is proposed that use of this device reduces the symptoms of gastroparesis such as nausea and vomiting and fosters improved gastric emptying.

Gastric Electrical Stimulation for Gastroparesis
Gastroparesis is a chronic motility disorder of the stomach characterized by gastric retention in the absence of mechanical obstruction. The main causes of gastroparesis are idiopathic, diabetic and postsurgical. Idiopathic gastroparesis refers to gastroparesis of unknown etiology. Diabetic gastroparesis is believed to be caused by chronic hyperglycemia which damages the vagus nerve. Gastroparesis that develops after surgery is called postsurgical gastroparesis (Camilleri, 2020; Zoll, et al., 2019; Pasricha, et al., 2017; Parkman, 2015).

Symptoms of gastroparesis include early satiety, nausea, vomiting, bloating, and upper abdominal discomfort. Postprandial vomiting (1–3 hours after meals) of undigested food is typical. Abdominal discomfort is of varying degrees and is not usually the predominant symptom. Symptoms may be persistent or present as episodic flares. Due to the symptoms, some patients will experience weight loss and malnutrition and, in severe cases, dehydration. There is also an overlap of symptoms with functional dyspepsia (Camilleri, 2020; Zoll, et al., 2019; Parkman, 2015).

The retrospective study by Friedenberg et al. (2013) studied the influence of race on symptom severity and quality of life in gastroparesis. The study included 44 (17%) nonwhites (33 African American and 11 Hispanic) and 211 (83%) whites. The study reported that nonwhite and white patients with gastroparesis differ in disease etiology and health care utilization. Nonwhite patients with gastroparesis secondary to diabetes was 55% compared with 19% of white patients ($p<0.001$). Additionally, 49% of nonwhite patients reported ≥ 4 gastroparesis-related emergency department visits and 42% reported more ≥ 4 gastroparesis related hospitalizations, as compared with 20% and 14% of white patients, respectively. The study concluded that nonwhite patients with gastroparesis were more likely to have diabetes as the etiology, have more severe symptoms, poorer QOL and utilized more health care resources than white patients.

The treatment of gastroparesis is guided by the goals of correcting fluid, electrolyte, and nutritional deficiencies; identifying and treating the cause of delayed gastric emptying (e.g., diabetes); and suppressing or eliminating symptoms. Primary medical management for gastroparesis includes dietary modification and pharmacologic therapy with prokinetic (metoclopramide and erythromycin) and antiemetic agents. Patients refractory to treatment are difficult to manage. Treatment may involve changing or combining medications; placement of a gastrostomy or jejunostomy tube for enteral feedings; or in severe cases, total parenteral nutrition (TPN) for brief periods (Camilleri, 2020; Zoll, et al., 2019; Parkman, 2015). Some patients, however, remain refractory to gastroparesis treatment.

Although proposed as a treatment for refractory gastroparesis, the exact mechanism of action of GES is not clearly known. The Enterra™ Therapy System (Medtronic, Inc., Minneapolis, MN) is a gastric electrical stimulator. According to the manufacturer, the Enterra Therapy system is composed of a neurostimulator or implanted pulse

generator (IPG), two implantable intramuscular leads and an external programming system. The intramuscular stomach leads are implanted laparoscopically on the greater curvature of the stomach. The IPG is implanted in a subcutaneous pocket typically created on the abdomen, and is then connected to the leads. The IPG provides the energy source that delivers the electrical pulse to the stomach muscle through the stomach leads. The generator stimulates the stomach muscle at a set of stimulation parameters determined by the physician (U.S. Food and Drug Administration [FDA], 2000b). The electrical stimulation produced by this device stimulates the stomach to contract and helps control the symptoms associated with gastroparesis, including nausea and vomiting (Medtronic Inc., 2017).

U.S. Food and Drug Administration (FDA): The Enterra Therapy System (Medtronic Inc., Minneapolis, MN) is a GES which received FDA marketing approval as a Class III medical device under the Humanitarian Device Exemption (HDE) on March 31, 2000. It is indicated for the treatment of chronic, intractable (drug refractory) nausea and vomiting secondary to gastroparesis of diabetic or idiopathic etiology. This system has not been evaluated for patients under age 18 or over age 70 (FDA, 2000b). According to the FDA, a humanitarian use device (HUD) is a device that is intended to benefit patients by treating or diagnosing a disease or condition that affects fewer than 4000 individuals in the United States per year. An HDE application is not required to contain the results of scientifically valid clinical investigations demonstrating that the device is effective for its intended purpose. However, the application, must contain sufficient information for the FDA to determine that the device does not pose an unreasonable or significant risk of illness or injury, and that the probable benefit to health outweighs the risk of injury or illness from its use, taking into account the probable risks and benefits of currently available devices or alternative forms of treatment. Additionally, the applicant must demonstrate that there are no comparable devices available to treat or diagnose the disease or condition, and that they could not otherwise bring the device to market (FDA, 2018).

Literature Review: The evidence in the published peer-reviewed medical literature examining the safety and effectiveness of permanent GES for the treatment of gastroparesis primarily consists of observational studies and case series and few randomized control trials (RCTs).

Ducrotte et al. (2020) conducted a multicenter, double-blind randomized controlled trial with crossover that studied the efficacy of GES in patients with refractory vomiting, with or without gastroparesis. Included patients (n=172) had chronic vomiting and/or nausea > 12 months that was related to type 1 or 2 diabetes mellitus, related to a surgical procedure (partial gastric resection surgery and/or vagotomy), or was idiopathic. Patients had normal or delayed gastric emptying with symptoms that were refractory to treatment and severe enough to affect the general condition of the patient. Patients didn't have evidence of a mechanical obstruction within the digestive tract or a neurologic disease. Patients were randomized to either the ON/OFF group (n=79) with four months of active stimulation followed by four months of sham stimulation or the OFF/ON group (n=93) with four months of sham stimulation followed by four months with active stimulation. Patients were examined at the end of each four month period (at five and nine months after implantation). Primary endpoints measured were vomiting score, ranging from 0 (daily vomiting) to 4 (no vomiting), and the quality of life, assessed by the Gastrointestinal Quality of Life Index scoring system. Secondary endpoints were changes in other digestive symptoms, nutritional status, gastric emptying, and control of diabetes. Final analysis in the intention to treat (ITT) population was carried out in 66 patients in the ON/OFF group and in 83 patients in the OFF/ON group. During both phases of the crossover study, vomiting scores were significantly higher in the group with the device on than the control group ($p<0.001$), in diabetic and nondiabetic patients. Vomiting scores increased significantly when the device was ON in patients with delayed ($p<0.01$) or normal gastric emptying ($p=0.05$). Gastric emptying was not accelerated during the ON period compared with the OFF period. Having the GES turned on was not associated with increased quality of life. A total of 101 adverse events were reported in the study, with 45 therapy or device -related events: abdominal wall pain at the implantation site (n=28), infections at the abdominal pouch level (n=16), hematoma (n=1). In three cases, the device-related adverse events were serious enough to prompt device removal. The authors concluded that GES is effective in reducing the frequency of refractory vomiting and nausea in a subset of patients with chronic vomiting. Further studies are needed to determine predictive factors of favorable response and the technique's cost effectiveness.

A 2018 Hayes Medical Technology Directory report evaluated the evidence (n=12 studies) on GES for the treatment of gastroparesis. The report evaluated three randomized crossover trials, six pretreatment/posttreatment studies, one nonrandomized comparative study, one comparative cohort study, and

one compilation of case series. Study sample sizes ranged from 18–233 patients. Patients were selected who had symptomatic gastroparesis refractory to medical treatment with diagnoses of diabetic gastric neuropathy or idiopathic gastroparesis. All patients underwent permanent implantation of a Medtronic Enterra GES system. In all of the reviewed studies, GES was used in conjunction with conventional treatments for gastroparesis, such as prokinetic and antiemetic drugs. The studies evaluated the efficacy and safety of GES for treatment of gastroparesis. The follow-up timeframe varied among studies, the longest follow-up being 4.7 years. The report found low quality evidence indicating that GES may improve gastroparesis symptoms and gastric emptying as well as decrease the need for nutritional support in some patients with refractory gastroparesis. However, GES was found to be safe with the device removal rate ranging from 7%–12% primarily related to stimulator implantation and shifting of the stimulator or electrical leads after implantation. It was noted that despite the low quality of the supportive evidence, GES may be an option for patients with debilitating gastroparesis that is refractory to medical treatment. The annual review in 2020, did not change the conclusions of the original review (Hayes, 2018).

McCallum et al. (2010) conducted a prospective, multicenter, double-blinded, randomized cross-over study (n=55) to evaluate the safety and efficacy of the Enterra gastric stimulation system in the treatment of intractable (drug-refractory) nausea and vomiting secondary to gastroparesis of diabetic etiology. The primary outcome measure was the reduction in weekly vomiting frequency when the device was turned on, relative to when the device was turned off during the blinded cross-over phase. Post-implantation, all patients had the stimulator turned on for six weeks and then were randomly assigned to groups that had consecutive three-month cross-over periods with the device on or off. After this period, the device was turned on in all patients with un-blinded follow-up for four months. Of the 55 subjects enrolled and implanted, 10 were not randomized. A total of 43 subjects completed the cross-over phase and 39 subjects completed 12-month visit follow up. Device-related adverse events included lead migration or dislodgements (n=3), device migrations (n=2), an implant site hematoma, and one implant site infection. The weekly vomiting frequency at 12 months decreased significantly when compared to baseline, with a median reduction of 67.8% ($p<0.001$). Gastric emptying was significantly improved at 12 months with a median retention at four hours of 20.5% compared with 46.5% at baseline ($p<0.001$). Although there were no statistical differences observed in the cross-over period, weekly vomiting frequency was reported to be somewhat better controlled during the on state than the off state. Study limitations include small sample size and loss to follow-up.

O'Grady et al. (2009) performed a meta-analysis of 13 studies evaluating GES for the treatment of medically refractory gastroparesis. Uncontrolled observational studies (n=12) and one blinded randomized control trial (RCT) (Abell, et al., 2003) were included. The findings reported from this review were that following GES, patients had statistically significant improvements in total symptom severity score ($p=0.01$), vomiting severity score ($p<0.0001$), and nausea severity score ($p<0.0001$). The device removal or reimplantation rate was 8.3%.

Case series, retrospective reviews and cohort studies with patient populations ranging from 9–214 support the findings that GES may significantly improve upper GI symptoms and reduce the need for nutritional support in some patients with refractory diabetic or idiopathic gastroparesis (Laine, et al., 2018; Shada, et al., 2018; Klinge, et al., 2017; Heckert, et al., 2016; McCallum, et al., 2011; Maranki, et al, 2008; Anand, et al., 2007; McCallum, et al., 2005).

Temporary GES: Temporary GES (tGES) or percutaneous stimulation has been investigated as a potential method for a less invasive trial prior to permanent GES insertion. With the endoscopic technique, temporary non-surgical leads are placed endoscopically on the gastric mucosa and connected to an external gastric stimulation device (Enterra; Medtronic). In temporary percutaneous GES (TPGES), two percutaneous unipolar leads are inserted through a plastic cannula and anchored by flexible wing-like tines to the submucosal tissue (Hasler, 2020; Abel, et al., 2019a; Abel, et al., 2019b; Atassi and Abel 2019; Abell, et al., 2015; Singh, et al., 2015). According to the manufacturer (Medtronic Inc., Minneapolis, MN) the Enterra II Neurostimulator is implanted beneath the skin in the lower abdominal region. The neurostimulator generates electrical pulses delivered by implanted leads in the antrum portion of the stomach muscle wall. The only lead that is listed as compatible to the device is the intramuscular lead which is designed for intramuscular implantation to deliver electrical current to the stomach muscle (Medtronic, 2017).

U.S. Food and Drug Administration (FDA): FDA approval for temporary gastric electrical stimulation was not found on the FDA site. A temporary GES can be carried out using temporary external leads that are primarily designed for external cardiac pacing. However, this represents an off-label use as temporary external leads are not FDA approved for this indication.

Literature Review: There is a paucity of studies in the published peer-reviewed medical literature evaluating temporary GES for gastroparesis or any other indication. Singh et al. (2015) published the results of a cohort study (n=551) which aimed to clarify the role of GES in gastroparesis-like syndrome (GLS), defined as gastroparesis-like symptoms with normal gastric scintigraphy. Inclusion criteria were as follows:

- gastroparesis symptoms of diabetic, surgically related or idiopathic etiology
- aged 18–70 years old
- symptoms of gastroparesis for ≥ one year
- refractory or intolerant to prokinetic and antiemetic drug classes
- chronic vomiting or nausea or severe dyspepsia like syndrome consistent with gastroparesis irrespective of gastric emptying test (GET) values

Patients were excluded if they were not candidates for endoscopic or surgical procedures or were pregnant. A total of 452 patients underwent gastric scintigraphy and were stratified into: delayed gastric emptying (n=273), normal gastric emptying (n=137), and rapid gastric emptying categories (n=42). Of the 551 patients in the larger cohort, 379 had tGES implantation using a temporary cardiac pacing lead (Medtronic model 6416). Outcomes measured were changes in gastric scintigraphy and total symptom score. Both components (lead and generator) were used off-label in this study. After tGES, two-hour gastric retention decreased for the delayed patients ($p<0.01$), and increased for normal and rapid patients ($p<0.001$). These changes were accompanied by improvements ($p<0.001$) in vomiting, nausea, and total symptom scores in all three subgroups. Study limitations include the uncontrolled study design and the possibility of the treatment benefit being due to a placebo effect. Although study results suggest that tGES may be effective for treating GLS, well-designed RCTs are need to support these findings.

Abell et al. (2011) published the results of a randomized, placebo-controlled, crossover trial (n=58) to measure the effects of endoscopically placed temporary GES (tGES) on gastroparesis symptoms. The study consisted of two consecutive, 4-day sessions (session 1 and session 2). Inclusion criteria were as follows:

- patients between the ages of 18 and 70 years, with a ≥ one-year history of gastroparesis symptoms from diabetic (n=13), postsurgical (n=7), or idiopathic (n=38) etiology
- gastroparesis symptoms refractory or intolerant to antiemetic drug classes with ≥ seven episodes of chronic vomiting and/or nausea per week, irrespective of gastric emptying time values

Patients with an active infection or pregnancy were excluded. Temporary GES using a temporary cardiac pacing lead (model 6414-200; Medtronic, Minneapolis, Minn) was provided to 37/58 enrolled patients (group A [n=21]; group B [n=16]). During session 1 treatment was activated for 72 continuous hours in group A, and likewise activated in group B during session 2. The primary outcome measure was a 50% improvement in baseline symptom values. Secondary outcomes were gastric emptying, electrogastrography, and quality of life measured at baseline and session close. An overall treatment effect of a slight, non-significant daily decrease in average vomiting scores ($p=0.116$) was observed by pooling stimulation effects across sessions. The single reported adverse event was dislodged electrodes for six patients in group A and seven in group B. Study limitations include the small sample size and the fact that patients were allowed to continue medication for nausea or pain (prokinetics, anti-emetics) during the trial. The small sample size and non-significant improvement in symptoms make it difficult to draw conclusions from this study.

Gastric Electrical Stimulation for Other Indications
The use of GES is currently under investigation for the treatment of obesity and type 2 diabetes mellitus (T2DM).

Obesity: GES has been proposed as a device therapy for the treatment of morbid obesity. GES for obesity is currently registered by the FDA as investigational. In Europe, however, GES is being used clinically to treat

obesity. Transneuronix, Inc., (Mt. Arlington, NJ), acquired in 2005 by Medtronic Inc. (Minneapolis, MN), developed the Transcend™ Gastric Stimulation System for obesity. This implantable gastric stimulator (IGS) has not been approved by the FDA. The device includes a pulse generator, an external programmer and a gastric stimulation lead, and is implanted laparoscopically in the subcutaneous tissue. The Transcend is intended to induce satiety by delaying gastric emptying (Greenway and Zheng, 2007).

A number of unresolved issues regarding the use of GES for treatment of obesity have been identified. The mechanism of action is unclear. Proposed possibilities include: a local enteric nervous system effect, an effect mediated by the autonomic nervous system, possible central nervous system changes and neurohormonal changes. Optimal stimulation patterns are unknown, as is the importance of the number of leads and the location of electrodes. Optimal screening of patients for GES for obesity has not yet been determined. Also, the best combination of behavioral, drug, device and surgical therapies has not been determined (Abell, et al., 2006). As a result, the use of a gastric pacing device for these indications remains under investigation.

Literature Review: GES for the treatment of obesity has been evaluated in case series, randomized controlled trials (RCTs) and systematic reviews. Paulus et al. (2020) conducted a multicenter, phase 1, open prospective cohort study in the Netherlands and the USA. The study assessed the following in patients with morbid obesity: the safety of the Exilis™ gastric electrical stimulation (GES) system, the setting adjustments for chronic use and the acute gastrointestinal (GI)/feeding effects. Patients were included in this study if they were weight stable, aged 21–64 years and had a body mass index (BMI) of 40–45 kg/m2 or 35–39.9 kg/m2 with at least one weight-related comorbidity (e.g., nonalcoholic steatohepatitis, hypertension, dyslipidemia, obstructive sleep apnea, arthrosis). If a patient was diagnosed with diabetes mellitus, the diagnosis had to be made within the last seven years, had to be currently treated with oral agents only and had to have an HbA1c ≤ 8%. Twenty morbidly obese patients (17 female, mean BMI of 40.8 ± 0.7 kg/m2) were implanted with the Exilis™ system followed by a two week recovery period prior to continuation of the study protocol. The study protocol included four amplitude titration visits (visits A, B, C, and D) occurring at weekly intervals. The amplitude titration visits were followed by two GI function test days performed in randomly assigned order and repeated twice (once with GES ON and once with GES OFF). Each GI function test day was preceded by a washout period (GES OFF) of seven days, and subjects were blinded to the assigned GES treatment. Testing at weeks 26 and 52 included simultaneous measurement of gastric emptying (using a breath test), gastric motility (SmartPill®), plasma concentrations of glucose and insulin, and food intake over a four hour period in the morning following an overnight fast. Impact of Weight on Quality of Life-Lite (IWQOL-Lite) and the Multi-purpose Short Form Survey-12 (SF-12) were used to measure quality of life. Both surveys were administered at screening visit, week 0, 13, 26, and 52 postoperatively.

The authors stated that there were not any serious adverse events in all 20 subjects, with the exception of incisional hernias which had to be corrected surgically (n=2). The other adverse events were mild and were related to the IPG pocket (seroma, infection, hernia) and are most likely due to the relatively superficial placement of the device. At the 26-week and 52 week follow-up, three and four subjects (respectively) had withdrawn from the study due to not reaching the desired effect. Most of the patients that withdrew from the study had a surgical revision to Roux-en-Y gastric bypass (RYGB) or laparoscopic sleeve gastrectomy (LSG). They were not included in further analysis. At week four, 13, and 26, a significant reduction in weight loss was observed ($p<0.01$) but not at week 52. At this time point, the mean excess weight loss (EWL) was 14.2 ± 4.5%. There was no significant differences between GES ON and OFF in gastric emptying halftime, food intake, insulin, and glucose (all $p>0.05$). Author noted limitations included possible adaptation to the signal which could have resulted in loss of efficacy and the lack of a control group. Additional limitations included the small patient population and only patients from the Netherlands and the USA were enrolled and the results may not be applicable to other races or ethnic groups. The study concluded that gastric electrical stimulation with the Exilis™ system can be considered as safe. However, no significant effect on food intake, gastric emptying, or gastric motility was observed. The reduction in weight loss with Exilis™ wasn't observed in the long term. Further electrophysiological research is needed to gain more insight in optimal stimulation parameters and lead localization. No health disparities were identified by the investigators.

Cha et al. (2014) performed a systematic review (n=31 studies/1367patients) of the evidence to evaluate the effect of different types of gastric electrical stimulation (GES) on obesity. Published studies investigating the effect of GES using the Tantalus and Transcend devices, as well as vagus nerve stimulation, were included.

Exclusion criteria for published studies were GES used for diseases other than obesity (e.g., gastroparesis); non-gastric stimulation, and non-clinical primary outcome. Studies were primarily non-randomized, with 4/31 randomized trials. In all studies, the generator was externalized and in most cases they were implanted in subcutaneous layers of the anterior abdominal wall. The electrodes connected to the generator were implanted in different locations of the stomach, depending on the type of GES. The primary outcome was weight loss, with secondary outcomes of appetite or satiety changes and biochemical marker changes. Almost all studies in each device group achieved statistically significant weight loss during the first 12 months. Only a small percentage of studies had a follow-up longer than one year, and found significant weight loss maintenance. Findings were inconsistent for secondary outcomes. Gastric penetration was the most common device-related complication. In general, the level of evidence was found to be low with few studies having a large population and low loss to follow-up. Results of studies in this systematic review suggest that GES may be effective for short-term weight loss. However well-designed studies with larger patient population and long-term follow up are needed to determine safety and effectiveness of the technology for this indication.

Shikora et al. (2009) conducted a randomized, double-blinded, placebo-controlled study (n=190), the Screened Health Assessment and Pacer Evaluation (SHAPE) trial. The SHAPE study compared gastric stimulation therapy (n=96) to a standard diet and behavioral therapy regimen (n=94) in a group of obese patients. Subjects were required to be 18–65 years of age and have a BMI of 35–55 kg/m^2. Exclusion criteria included pregnancy, previous gastrointestinal bariatric surgery, the presence of other electrostimulation devices (e.g., pacemakers), gastrointestinal motility disorders, peptic ulcer disease, and clinically significant comorbidities such as poorly controlled diabetes. Follow-up occurred monthly for 12 months. The difference in excess weight loss (%EWL) between the control group and the treatment group was not found to be statistically significant (p=0.717) at 12 months of follow-up. These results suggest that this technology is not effective in achieving significant weight loss in severely obese individuals.

Shikora (2004) reported an update of two U.S. clinical trials for gastric stimulation in obesity. The first was an RCT in 2000 that included patients (n=103) age 18–50 who had a BMI of 40–55 kg/m² (mean 46 kg/m²). No statistical difference in the weight loss between study and control groups was found at six-month follow-up. At 29 months, the overall mean EWL increased to > 12.0%. A total of 69 patients were lost to follow-up.

The second trial (n=30), the Dual-Lead Implantable Gastric Electrical Stimulation Trial (DIGEST), was a non-randomized, open-label study of patients with a BMI 40–55 kg/m² or 35–39 kg/m² and one or more significant comorbidities. At the 12-month follow-up point, 71% of participants lost weight (54% lost > 10% of excess, and 29% lost > 20% excess). At the 16-month follow-up, mean EWL was 23%.

Several case series (n=11–91 patients) have investigated the implantation of GES for the treatment of obesity reporting varying rates of excess weight loss and improvement of comorbidities (Bohdjalian, et al., 2009; Miller, et al., 2006; Cigaina, et al., 2003). In addition to the lack of randomization, in general studies have been limited by small sample sizes and short-term follow-up.

There is insufficient evidence in the published scientific literature to support the use of gastric pacing for the treatment of morbid obesity.

Type 2 Diabetes Mellitus (T2DM): The effect of GES on HbA1c and blood glucose levels, along with changes in body weight is also being investigated. The DIAMOND® (Diabetes Improvement and MetabOlic Normalization Device), formerly known as the TANTALUS device, has been developed by MetaCure, Inc. (Kfar-Saba, Israel). The DIAMOND device consists of three pairs of bipolar electrodes. One pair is attached to the gastric fundus and the other two pairs are attached to the anterior and the posterior antrum of the stomach. The electrodes are implanted laparoscopically and connected to a pulse generator inserted into the subcutaneous tissue of the abdomen. The pulse generator uses a rechargeable battery as an external power source. The delivered electrical signal characteristics are set by a programmer within the first week after the implantation (Lebovitz, et al., 2015). Clinical trials are now being conducted using this device for overweight and obese patients with type 2 diabetes.

Literature Review: The evidence in the published peer-reviewed medical literature examining the safety and effectiveness of GES for obese patients with T2DM consists of few case series (Lebovitz, et al., 2015;

Bohdjalian, et al., 2009; Policker, et al., 2009; Sanmiguel, et al., 2009). Patient populations in these studies have ranged from 14–61, with a follow-up of primarily six–12 months. Although preliminary results suggest that GES may improve glycemic control and induce weight loss in patients with T2DM, additional evidence in the form of well-designed RCTs is needed to confirm these findings.

Professional Societies/Organizations
American College of Gastroenterology (ACG): The ACG published guidelines stated that gastric electrical stimulation may be considered for compassionate treatment in patients with refractory symptoms such as nausea and vomiting. Symptom severity and gastric emptying have been shown to improve in patients with diabetic gastroparesis (Camilleri, et al., 2013).

National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK): The NIDDK stated that gastric electrical stimulation may be effective for some people whose nausea and vomiting do not improve with dietary changes or medications (NIDDK, 2018).

Use Outside of the US
The National Institute for Health and Care Excellence (NICE) (United Kingdom) issued a statement in 2014 which supported the use of gastric electrical stimulation for gastroparesis. NICE stated that "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" (NICE, 2014).

Medicare Coverage Determinations

	Contractor	Policy Name/Number	Revision Effective Date
NCD		No National Coverage Determination found	
LCD		No Local Coverage Determination found	

Note: Please review the current Medicare Policy for the most up-to-date information.

Coding/Billing Information

Note: 1) This list of codes may not be all-inclusive.
2) Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

Intractable Nausea and Vomiting Secondary to Gastroparesis:

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

CPT®* Codes	Description
43647	Laparoscopy, surgical; implantation or replacement of gastric neurostimulator electrodes, antrum
43881	Implantation or replacement of gastric neurostimulator electrodes, antrum, open
64590	Insertion or replacement of peripheral or gastric neurostimulator pulse generator or receiver, direct or inductive coupling
95980	Electronic analysis of implanted neurostimulator pulse generator system (eg, rate, pulse amplitude and duration, configuration of wave form, battery status, electrode selectability, output modulation, cycling, impedance and patient measurements) gastric neurostimulator pulse generator/transmitter; intraoperative, with programming
95981	Electronic analysis of implanted neurostimulator pulse generator system (eg, rate, pulse amplitude and duration, configuration of wave form, battery status, electrode selectability, output modulation, cycling, impedance and patient measurements) gastric neurostimulator pulse generator/transmitter; subsequent, without reprogramming

CPT®* Codes	Description
95982	Electronic analysis of implanted neurostimulator pulse generator system (eg, rate, pulse amplitude and duration, configuration of wave form, battery status, electrode selectability, output modulation, cycling, impedance and patient measurements) gastric neurostimulator pulse generator/transmitter; subsequent, with reprogramming

Any Other Indication:

Considered Experimental/Investigational/Unproven when used to report temporary gastric electric stimulation, open or laparoscopic implantation or replacement of gastric stimulation electrodes, lesser curvature (i.e., morbid obesity):

CPT®* Codes	Description
43659	Unlisted laparoscopy procedure, stomach
43999	Unlisted procedure, stomach

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