



# Cigna Medical Coverage Policy

**Subject** **Gastric Pacing/Gastric Electrical Stimulation (GES)**

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## Table of Contents

Coverage Policy .....	1
General Background .....	1
Coding/Billing Information .....	5
References .....	6

## Hyperlink to Related Coverage Policies

[Bariatric Surgery](#)  
[Electrical Stimulation Therapy](#)  
[and Devices](#)  
[Nutritional Support](#)

## INSTRUCTIONS FOR USE

The following Coverage Policy applies to health benefit plans administered by Cigna companies. Coverage Policies are intended to provide guidance in interpreting certain **standard** Cigna benefit plans. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document **always supersedes** the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations. Proprietary information of Cigna. Copyright ©2013 Cigna

## Coverage Policy

Cigna covers gastric electrical stimulation (GES) or gastric pacing (e.g., Enterra™ Therapy) as 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.

Cigna does not cover gastric electrical stimulation (GES) or gastric pacing for any other indication because it is considered experimental, investigational or unproven.

## General Background

Gastric electrical stimulation (GES) (e.g., Enterra™ Therapy), also referred to as gastric pacing, has been proposed for patients with gastroparesis who are refractory to medical treatment. 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.

A gastric pacemaker utilizes an external programmer and implanted electrical leads to the stomach. It transmits low-frequency, high-energy electrical stimulation to the stomach to entrain and pace the gastric slow waves to foster satiety. It has also been proposed for use in patients with morbid obesity.

## Gastric Electrical Stimulation for Gastroparesis

Gastroparesis is a chronic motility disorder of the stomach characterized by gastric retention in the absence of mechanical obstruction. Diabetes mellitus is the most common disease associated with gastroparesis. Diabetic gastroparesis is believed to be a form of neuropathy of the vagus nerve. Hyperglycemia can also cause delayed

gastric emptying. Idiopathic gastroparesis is the second most common type of gastroparesis, followed by postsurgical gastroparesis (Abell, et al., 2006; American Gastroenterological Association [AGA], 2004; Parkman, et al., 2003).

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. The symptoms of gastroparesis are nonspecific and may mimic other conditions such as ulcer disease, partial gastric or small bowel obstruction, gastric cancer, gallbladder or pancreatic disorders. There is also an overlap of symptoms with functional dyspepsia (Abell, et al., 2006; AGA, 2004; Parkman, et al., 2003).

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 (Abell, et al., 2006; AGA, 2004; Parkman, et al., 2003). 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, an implantable intramuscular lead and an external programming system. The system uses the implanted neurostimulator to deliver electrical impulses to nerves in the stomach. 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., 2007).

**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, 2000). 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 HUD application is not required to contain the results of scientifically valid clinical investigations demonstrating that the device is effective for its intended purpose (FDA, 2003).

**Literature Review:** The evidence in the published peer-reviewed medical literature examining the safety and effectiveness of GES for the treatment of gastroparesis primarily consists of observational studies and case series and few randomized control trials (RCTs). 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 (McCallum, et al., 2010). 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 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 (McCallum, et al., 2011; Islam et al., 2008; Anand, et al., 2007; Maranki, et al., 2007; McCallum, et al., 2005; Lin, et al., 2005; Lin, et al., 2004).

### **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 (ECRI, 2010). 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., 2006a). 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 randomized controlled trials (RCTs). The Screened Health Assessment and Pacer Evaluation (SHAPE) trial by Shikora et al. (2009) compared gastric stimulation therapy to a standard diet and behavioral therapy regimen in a group of obese patients. 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 (2004a) reported an update of the 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/m<sup>2</sup> (mean 46 kg/m<sup>2</sup>). 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/m<sup>2</sup> or 35–39 kg/m<sup>2</sup> 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) 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., 2006; 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).

Clinical trials are now being conducted using this device for overweight and obese patients with type 2 diabetes (ECRI, 2012).

**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 (Bohdjalian, et al., 2009; Policker, et al., 2009; Sanmiguel, et al., 2009). Patient populations in these studies have ranged from 14–50, with a follow-up of 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**

The National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) lists gastric electrical stimulation as an option available to people whose nausea and vomiting do not improve with medications. The NIDDK also states, further studies will help determine who will benefit most from this procedure, which is available in a few centers across the United States (NIDDK, 2007).

In a technical review of the diagnosis and treatment of gastroparesis, the American Gastroenterology Association (AGA) (2004), determined that there are a number of issues with gastric electrical stimulation that require further investigation and evaluation. These include confirmation of the effectiveness of gastric stimulation in a long-term, blinded fashion, identification of patients most likely to respond, and determination of optimal electrode position and stimulation parameters. In a technical review on obesity (AGA, 2002), the AGA stated that randomized controlled trials are needed to determine the effectiveness and safety of new surgical approaches to obesity (gastric pacing, laparoscopic techniques).

### **Use Outside of the US**

The Australia and New Zealand Horizon Scanning Network's (ANZHSN) scanning program is a collaborative Commonwealth and State initiative guided by the Health Policy Advisory Committee on Technology (HealthPACT). HealthPACT provides jurisdictions with evidence-based advice on emerging technologies. This information is used to inform jurisdiction financing decisions and to assist in the managed introduction of new technologies. According to HealthPACT, it is unclear how widely Enterra therapy is employed for the treatment of gastroparesis in European countries, although it does seem to be used in the U.K. at present. In March 2002, Enterra Therapy received the Conformité Européene (CE) mark making the device commercially available in Europe (HealthPACT, 2006).

A 2006 Horizon Scanning report prepared by the Australian safety and Efficacy Register of New Interventional Procedures – Surgical (ASERNIP-S) for HealthPACT provided recommendations on the Enterra device. Stage of development was determined to be “not yet emerged” in Australia, with limited use in Europe and the US. The Enterra system was not listed or registered in the Australian Register of Therapeutic Goods (ARTG). The HealthPACT advisory states that “the available evidence regarding the Enterra system provides sufficient encouragement and the potential to improve the symptoms and overall quality of life of patients with gastroparesis to warrant the conduct of more robust randomized multi-center research, including an economic evaluation. It is not recommended that this procedure be used outside the context of a clinical trial protocol” (HealthPACT, 2006).

The Transcend IGS (manufactured by Transneuronix; Medtronic acquired Transneuronix in July 2005) is being used to treat obesity in Europe and was granted CE mark approval in 2001 (HealthPACT, 2005).

A 2005 Horizon Scanning Prioritizing Summary prepared by ASERNIP-S for the Health Policy Advisory Committee on Technology (HealthPACT) provided recommendations on the Transcend device. Stage of development in Australia was deemed experimental and use limited in Italy, Austria, Sweden, Germany, Belgium, France, and a trial is underway in the USA. It was reported that “the use of gastric electrical stimulation for the treatment of obesity offers a potentially safe and effective alternative for patients who are not suited for surgery. Based on the evidence available, it is proposed that this technology is monitored until the publication of RCT results” (HealthPACT, 2005). A 2009 update found the new evidence to be in line with inconsistent results of previous studies and stated that “given the inconsistency of results and the lack of development, further assessment will not be conducted” (HealthPACT, 2009).

The National Institute for Health and Care Excellence (NICE) (United Kingdom) issued a statement in 2004 which did not support the use of gastric electrical stimulation for gastroparesis due to the lack of evidence regarding the safety and efficacy of its use (NICE, 2004).

## **Summary**

The evidence from few randomized controlled trials and a number of case series in the published peer-reviewed medical literature indicates that gastric electrical stimulation (GES) (e.g., Enterra Therapy) may be a safe and effective option for those patients with intractable nausea and vomiting secondary to gastroparesis who have failed all other treatments. The use of GES or gastric pacing remains unproven for the treatment of other conditions such as obesity and type 2 diabetes mellitus (T2DM). Optimal patient selection criteria, electrode position, lead number and stimulation patterns have not yet been determined. Additional well-designed studies are needed to demonstrate the safety and effectiveness of GES for these indications.

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## **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:**

#### **Covered when medically necessary:**

<b>CPT®* Codes</b>	<b>Description</b>
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
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:**

**Experimental/Investigational/Unproven/Not Covered when used to report open or laparoscopic implantation or replacement of gastric stimulation electrodes, lesser curvature (i.e., morbid obesity):**

<b>CPT® Codes</b>	<b>Description</b>
43659	Unlisted laparoscopy procedure, stomach
43999	Unlisted procedure, stomach

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