



CIGNA MEDICAL COVERAGE POLICY

The following Coverage Policy applies to all health benefit plans administered by CIGNA Companies including plans formerly administered by Great-West Healthcare, which is now a part of CIGNA.

Subject Gastric Pacing/Gastric Electrical Stimulation (GES)

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Table of Contents

Coverage Policy	1
General Background	1
Coding/Billing Information	4
References	5
Policy History	7

Hyperlink to Related Coverage Policies

- Antiemetics -Oral and Topical Serotonin-3 Receptor Antagonists
- Bariatric Surgery
- Electrical Stimulators
- Nutritional Support
- Wireless Gastrointestinal Motility Monitoring System (SmartPill®)

INSTRUCTIONS FOR USE

Coverage Policies are intended to provide guidance in interpreting certain **standard** CIGNA HealthCare benefit plans. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement (GSA), 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 supercedes** 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. Proprietary information of CIGNA. Copyright ©2011 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): 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. 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) 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 (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/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 ($n=11–91$) 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 TANTALUS II system has been developed by Metacure (St. Louis, MO). Clinical trials are now being conducted using this device for overweight and obese patients with type 2 diabetes (ECRI, 2010).

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).

The National Institute for Clinical 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

Although evidence supporting its use is not strong, the 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.

Coding/Billing Information

Note: This list of codes may not be all-inclusive.

Covered when medically necessary:

CPT [®] * Codes	Description
43647	Laparoscopy, surgical; implantation or replacement of gastric neurostimulator electrodes, antrum
43648	Laparoscopy, surgical; revision or removal of gastric neurostimulator electrodes, antrum
43881	Implantation or replacement of gastric neurostimulator electrodes, antrum, open
43882	Revision or removal of gastric neurostimulator electrodes, antrum, open
64590	Insertion or replacement of peripheral or gastric neurostimulator pulse generator or receiver, direct or inductive coupling
64595	Revision or removal of peripheral or gastric neurostimulator pulse generator or receiver
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

HCPCS Codes	Description
E0765	FDA approved nerve stimulator, with replaceable batteries, for treatment of nausea and vomiting

ICD-9-CM Diagnosis Codes	Description
536.2	Persistent vomiting
536.3	Gastroparesis
787.01-787.03	Nausea and vomiting

Experimental/Investigational/Unproven/Not Covered:

CPT* Codes	Description
0155T	Laparoscopy, surgical, implantation or replacement of gastric stimulation electrodes, lesser curvature (i.e., morbid obesity)
0156T	Laparoscopy, surgical, revision or removal of gastric stimulation electrodes, lesser curvature (i.e., morbid obesity)
0157T	Laparotomy, implantation or replacement of gastric stimulation electrodes, lesser curvature (i.e., morbid obesity)
0158T	Laparotomy, revision or removal of gastric stimulation electrodes, lesser curvature (i.e., morbid obesity)

ICD-9-CM Diagnosis Codes	Description
278.00	Obesity, unspecified
278.01	Morbid obesity
V85.35	Body Mass Index 35.0-35.9, adult
V85.36	Body Mass Index 36.0-36.9, adult
V85.37	Body Mass Index 37.0-37.9, adult
V85.38	Body Mass Index 38.0-38.9, adult
V85.39	Body Mass Index 39.0-39.9, adult
V85.4	Body Mass Index 40 and over, adult

*Current Procedural Terminology (CPT®) © 2010 American Medical Association: Chicago, IL.

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Policy History

Pre-Merger Organizations	Last Review Date	Policy Number	Title
CIGNA HealthCare	6/15/2008	0103	Gastric Pacing/Gastric Electrical Stimulation (GES)
Great-West Healthcare	3/12/2007	05.279.02	Gastric Electrical Stimulation

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