GASTRIC ELECTRICAL STIMULATION FOR GASTROPARESIS

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INSTRUCTIONS:

“Medical Policy assists in administering UCare benefits when making coverage determinations for members under our health benefit plans. When deciding coverage, all reviewers must first identify enrollee eligibility, federal and state legislation or regulatory guidance regarding benefit mandates, and the member specific Evidence of Coverage (EOC) document must be referenced prior to using the medical policies. In the event of a conflict, the enrollee's specific benefit document and federal and state legislation and regulatory guidance supersede this Medical Policy. In the absence of benefit mandates or regulatory guidance that govern the service, procedure or treatment, or when the member’s EOC document is silent or not specific, medical policies help to clarify which healthcare services may or may not be covered. This Medical Policy is provided for informational purposes and does not constitute medical advice. In addition to medical policies, UCare also uses tools developed by third parties, such as the InterQual Guidelines®, to assist us in administering health benefits. The InterQual Guidelines are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice. Other Policies and Coverage Determination Guidelines may also apply. UCare reserves the right, in its sole discretion, to modify its Policies and Guidelines as necessary and to provide benefits otherwise excluded by medical policies when necessitated by operational considerations.”
**POLICY DESCRIPTION:**

This medical policy provides information of Gastric electrical stimulation (GES) therapy for the treatment of patients with chronic gastroparesis, a disorder in which there is delayed gastric emptying without evidence of mechanical obstruction, following the ingestion of food. Patients with gastroparesis often experience nausea, vomiting, early satiety, distension/bloating, and epigastric pain and burning. The electrodes of a gastric electrical stimulator (also called gastric pacing) are implanted on the stomach through a surgical procedure to deliver electrical impulses to the gastric muscles with the objective of stimulating gastric activity and, thereby, improving stomach emptying and reducing the frequency and severity of symptoms.

**COVERAGE RATIONALE / CLINICAL CONSIDERATIONS:**

Gastric electrical stimulation and gastric pacing (gastric pacemaker) using the Enterra Therapy System™ is considered MEDICALLY NECESSARY for the treatment of chronic, intractable (drug refractory) nausea and vomiting secondary to gastroparesis of diabetic or idiopathic etiology.

As a humanitarian approved device, the Enterra Therapy System™ may only be used in facilities that have an Institutional Review Board (IRB) to supervise clinical testing of the device.

Gastric electrical stimulation is considered EXPERIMENTAL AND/OR INVESTIGATIONAL in all other indications including, but not limited to the treatment of obesity.

**Clinical Considerations:**

**Indications:**
- Symptomatic gastroparesis ≥ one year, as documented by an initial gastric emptying test; and
- Refractory or intolerant to at least two anti-emetic and prokinetic drug classes, and
- On stable medical therapy and, if applicable, stable nutritional support during the month prior to initiation of therapy, and
- Delayed gastric emptying, defined by > 60% retention at two hours and > 10% retention at four hours, as measured by standardized gastric emptying testing, and
- As a humanitarian approved device, the Enterra Therapy System™ may only be used in facilities that have an Institutional Review Board (IRB) to supervise clinical testing of the device.

**Contraindications:** The following are relative and absolute contraindications to the use of gastric stimulation:
- Pregnancy,
- Peritoneal dialysis,
- Primary or secondary eating disorders,
- Psychogenic vomiting,
- Implanted devices that are electrically or magnetically activated (e.g., cardiac pacemakers, automatic Cardioverter defibrillators, drug infusion pumps, cochlear implants),
- Ferromagnetic metal objects (e.g., cerebral aneurysm clips, intraocular metallic foreign body, prostheses, screws),
- Diathermy (e.g., shortwave diathermy, microwave diathermy, or therapeutic ultrasound diathermy).

The Enterra system is not appropriate for patients with gastric obstruction or pseudo-obstruction, prior
gastric resection, fundoplication, eating disorders, history of seizures, primary swallowing disorders, chemical dependency, or psychogenic vomiting.

The manufacturer states that the safety of the Enterra device has not been established for patients who are pregnant or for those who are under the age of 18 or over the age of 70.

**Possible Complications:** Adverse events reported by the device manufacturer include infection, stomach wall perforation, migration/erosion of the neurostimulator, undesirable change in stimulation, hemorrhage, hematoma, gastrointestinal complications, migration of the lead, persistent pain and/or seroma at the neurostimulator site, allergenic or immune system response to implanted materials, feeding tube complications, dehydration, and loss of therapeutic effect (Medtronic, 2007). Irritation and erosion of the skin over the generator implantation site were also relatively common.

**BACKGROUND:**

Gastroparesis, also referred to as gastric stasis, is a common gastrointestinal motility disorder occurring in approximately 4% of the population in the United States (Hasler et al., 2007). It is defined by delayed gastric emptying without evidence of mechanical obstruction. Patients may experience symptoms of frequent nausea and vomiting, early satiety, bloating, postprandial fullness, and epigastric pain and burning (Camilleri and Prather, 1998; Hasler et al., 2007). The most common cause of gastroparesis is diabetes. Gastroparesis may also occur in association with viral infections, anorexia nervosa or bulimia, medications that slow contractions in the intestines (anticholinergics and narcotics), gastroesophageal reflux disease, smooth muscle disorders (e.g., amyloidosis, scleroderma), nervous system diseases (e.g., Parkinson’s), and metabolic disorders (e.g., hypothyroidism) (NDDIC, 2007). Gastroparesis may also develop after vagotomy and gastric drainage operations or may be present in the absence of other disease (idiopathic gastroparesis) (Quigley et al., 2001).

Diabetes mellitus frequently results in gastrointestinal disorders, and hyperglycemia is, in itself, a physiologic cause of delayed gastric emptying; but diabetic gastroparesis is a common cause of gastroparesis in diabetic patients, and is associated with damage to the vagus nerve. Gastropathy may cause persistent vomiting, which contributes to poor glycemic control, and these patients may require frequent hospitalization due to hypoglycemia or hyperglycemia, electrolyte imbalance, or other complications of their disease (Shen and Soffer, 2000; NDDIC, 2007).

Gastroparesis interferes with the normal function of the stomach, which is made to contract and empty by the coordinated electrical and physical activity of its muscles. Recent studies demonstrated that the interstitial cells of Cajal, the pacemaker cells of the gastrointestinal system, are reduced in patients with gastroparesis (Hasler et al., 2007). Failure of the stomach to empty substantially within the normal time interval of approximately 2 hours leads to the chronic nausea and repeated vomiting that are the symptoms of gastroparesis. In addition to the great physical discomfort suffered by these patients, poor nutrition, and the inability to attend work, school, or social activities severely limits their lifestyles (Shen and Soffer, 2000; Abrahamsson et al., 2007; NDDIC, 2007).

The diagnosis of gastroparesis involves upper endoscopy to visualize any macroscopic anomalies, an ultrasound to rule out gallbladder disease or pancreatitis, a barium x-ray, and gastric emptying documented by scintigraphic analysis. (Ejskjaer et al., 1999).
The patient with gastroparesis typically is managed first with dietary modification to a low-fat, low-fiber diet, since high-fat meals are normally retained in the stomach for a longer period than low-fat meals, and fibrous foods are difficult to digest and can form a bezoar if stomach emptying time is prolonged. If dietary intervention alone is not successful, it may be supplemented with prokinetic drug therapy, which involves the use of cholinergic drugs to enhance gastric emptying. Prokinetic therapy may control the symptoms of nausea and vomiting, due either to improved gastric emptying or central antiemetic effects. However, these prokinetic drugs are associated with a number of serious complications. Antiemetic therapy may be added to prokinetic therapy if the symptoms of nausea are not controlled. The phenothiazine derivatives can be given orally, intramuscularly, or intravenously but may cause sedation, especially when given with metoclopramide. The antiemetic effects of the antiserotonergic drugs ondansetron, granisetron, and dolasetron have been demonstrated in patients receiving chemotherapy; however, their side effects and extremely high cost have limited their role in the treatment of chronic symptoms. If these dietary and pharmacological approaches fail, surgical approaches such as the placement of a gastrostomy for venting are attempted, with or without the placement of a jejunostomy for feeding. Finally, total parenteral nutrition can be used on a temporary basis for highly debilitated patients until a surgical option can be considered (Rabine and Barnett, 2001).

Electrical stimulation of the gastric musculature has been introduced as an alternative to drugs or surgery for treatment of patients with gastroparesis (Abrahamsson et al., 2007). It has been hypothesized that electrical stimulation of the gastric musculature could result in paced, coordinated gastric contractions similar to those seen occurring at approximately 3 cycles per minute (cpm) in the normal stomach. Early feasibility studies suggested that gastric stimulation could result in production or “entrainment” of gastric contraction wave activity (Miedema et al., 1992; Eagon and Soper, 1993; McCallum et al., 1998).

The Enterra® Therapy System, formerly named Gastric Electrical Stimulation (GES) System (Medtronic Inc.), is currently the only gastric pacing system approved for marketing by the Food and Drug Administration (FDA); it is approved under a Humanitarian Device Exemption (HDE). This device delivers timed electrical impulses to the gastric muscles. These electrical impulses are intended to stimulate gastric myoelectric activity, with the goal of improving stomach emptying and relieving symptoms such as nausea and vomiting.

**REGULATORY STATUS:**

1. **U.S. FOOD AND DRUG ADMINISTRATION (FDA):**
   The only gastric electrical stimulation (GES) device for gastroparesis treatment approved for marketing in the United States is the Enterra® Therapy System (Medtronic Inc.). On March 31, 2000, the FDA approved a Humanitarian Device Exemption (HDE) for the marketing of the Enterra system for the treatment of chronic, intractable or drug-refractory nausea and vomiting secondary to paresis of diabetic or idiopathic etiology (FDA, 2000b; FDA, 2008a). The HDE application is not required to contain the results of scientifically valid clinical investigations demonstrating that the device is effective for its intended purpose. The application, however, 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 no comparable devices are available to treat or
diagnose the disease or condition, and that they could not otherwise bring the device to market. The labeling must state that the effectiveness of the device for the specific indication has not been demonstrated (FDA, 2008b).

The marketing of this device is subject to the FDA’s “Conditions of Approval.” The initial use of this device has been limited to 4000 patients, and specific, strict documentation and reporting requirements are also required. The Enterra system must be approved by the Institutional Review Board (IRB) of the facility in which it is to be used (FDA, 2000b).

In Europe, the gastric stimulation device received CE Marking in 2002 (Abrahamsson et al., 2007).

2. CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS):
CMS has not established a National Coverage Determination (NCD) policy that addresses gastric electrical pacing.

Local Coverage Article for Enterra® Gastric Electrical Stimulation System, Humanitarian Device Exemption R2 (A51754)

This article from “Medicare A News,” Issue 2105 dated August 22, 2012 and “Medicare B News,” Issue 282 dated November 20, 2012 is being updated. When billing for Enterra® Services, HCPCS codes C1883, C1897, and L8680 are covered.

The Enterra® “Gastric Electrical Stimulation (GES) System Greater Curvature” is a device used for the treatment of severe and medically intractable gastroparesis associated with significant and/or life-threatening complications such as inanition. Enterra® received Food and Drug Administration (FDA) approval under the Humanitarian Device Exemption (HDE) regulations in 2000 for a single indication: “drug-refractory nausea and vomiting associated with gastroparesis of diabetic or idiopathic origin.”

This device is not approved for the treatment of obesity and it is not appropriate to use CPT codes 43648, 43881, 43882, 64595 for procedures associated with this device. Note that FDA regulations require approval prior to use of both the system and the indication for implantation by the implanting facility’s institutional review board (IRB).

Medicare may cover the use of this system only when the following two conditions are met:

- The patient’s medical record documents severe and chronic gastroparesis of diabetic or idiopathic origin, refractory to drug and other reasonable therapeutic interventions;
- The patient’s medical record documents the implanting facility’s institutional review board (IRB) approval for implantation of the system for one of the specific indications listed in the preceding bullet.

When the implantation of the Enterra® GASTRIC ELECTRICAL STIMULATION System has been covered under the above provisions, then subsequent necessary electronic analysis and programming may be submitted by CPT code 95980, 95981, and 95982.

3. MINNESOTA DEPARTMENT OF HUMAN SERVICES (DHS):
Minnesota DHS does not have a policy statement regarding gastric electrical stimulation in its Provider Manual or other specific provider references.
**CLINICAL EVIDENCE:**

**SUMMARY:**

There is limited available published evidence from studies of fair to moderate quality suggesting that permanent gastric electrical stimulation can consistently relieve gastroparesis symptoms and may eliminate or reduce the need for nutritional support in some patients with medically refractory gastroparesis. This therapy may also improve gastric emptying in some patients. In patients with diabetes, glycemic control may improve. The treatment benefit may be maintained for at least 3 years, which is the longest follow-up available in the reviewed studies. However, the available studies had a number of methodological weaknesses, including small numbers of patients, and most lacked blinded assessment of outcome measures and a placebo control. Additional studies are needed to establish patient selection criteria, stimulation parameters, and long-term safety. In all of the studies, patients continued antiemetic and/or prokinetic medication, although medication use was sometimes reduced during the study.

**APPLICABLE CODES:**

The Current Procedural Terminology (CPT®) codes and HCPCS codes listed in this policy are for reference purposes only. Listing of a service or device code in this policy does not imply that the service described by this code is a covered or non-covered health service. The inclusion of a code does not imply any right to reimbursement or guarantee claims payment. Other medical policies and coverage determination guidelines may apply.

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<th>HCPCS Codes</th>
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<td>536.3</td>
<td>Gastroparesis</td>
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<tr>
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<td>249.61</td>
<td>Secondary diabetes mellitus with neurological manifestations, uncontrolled</td>
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<td>Diabetes with neurological manifestations, type ii or unspecified type, not stated as uncontrolled</td>
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<tr>
<td>250.61</td>
<td>Diabetes with neurological manifestations, type i [juvenile type], not stated as uncontrolled</td>
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<tr>
<td>250.62</td>
<td>Diabetes with neurological manifestations, type ii or unspecified type, uncontrolled</td>
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<td>250.63</td>
<td>Diabetes with neurological manifestations, type i [juvenile type], uncontrolled</td>
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<tr>
<td>536.2</td>
<td>Persistent vomiting</td>
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<tr>
<th>ICD-9-CM Diagnosis Codes</th>
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<th>CPT® Codes</th>
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<tr>
<td>43647</td>
<td>Laparoscopy, surgical; implantation or replacement of gastric neurostimulator electrodes, antrum</td>
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<td>64590</td>
<td>Insertion or replacement of peripheral or gastric neurostimulator pulse generator or receiver, direct or inductive coupling</td>
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<td>95980</td>
<td>Electronic analysis of implanted neurostimulator pulse generator system (e.g., rate, pulse</td>
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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 (e.g., 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, without reprogramming

95982
Electronic analysis of implanted neurostimulator pulse generator system (e.g., 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

C1767
Generator, neurostimulator (implantable), non-rechargeable

C1778
Lead, neurostimulator (implantable)

C1883
Adaptor/extension, pacing lead or neurostimulator lead (implantable)

C1897
Lead, neurostimulator test kit (implantable)

L8680
Implantable neurostimulator electrode, each

CPT® is a registered trademark of the American Medical Association.

REFERENCES:


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