**Protocol**

**Gastric Electrical Stimulation**

(70173)

<table>
<thead>
<tr>
<th>Medical Benefit</th>
<th>Effective Date: 04/01/13</th>
<th>Next Review Date: 11/18</th>
</tr>
</thead>
<tbody>
<tr>
<td>Preauthorization</td>
<td>No</td>
<td>Review Dates: 01/07, 03/08, 03/09, 01/10, 01/11, 01/12, 01/13, 01/14, 11/14, 11/15, 11/16, 11/17</td>
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**Preauthorization is not required.**

The following protocol contains medical necessity criteria that apply for this service. The criteria are also applicable to services provided in the local Medicare Advantage operating area for those members, unless separate Medicare Advantage criteria are indicated. If the criteria are not met, reimbursement will be denied and the patient cannot be billed. Please note that payment for covered services is subject to eligibility and the limitations noted in the patient’s contract at the time the services are rendered.

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

**Description**

Gastric electrical stimulation (GES) is performed using an implantable device designed to treat chronic drug-refractory nausea and vomiting secondary to gastroparesis of diabetic, idiopathic, or postsurgical etiology. GES has also been investigated as a treatment of obesity. The device may be referred to as a gastric pacemaker.

**Summary of Evidence**

For individuals who have gastroparesis who receive GES, the evidence includes randomized controlled trials (RCTs) and systematic reviews. Relevant outcomes are symptoms and treatment-related morbidity. Five crossover RCTs have been published. A 2017 meta-analysis of these five RCTs did not find a significant benefit of GES on the severity of symptoms associated with gastroparesis. Patients generally reported improved symptoms at follow-up whether or not the device was turned on, suggesting a placebo effect. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have obesity who receive GES, the evidence includes one published RCT. Relevant outcomes are change in disease status and treatment-related morbidity. The SHAPE trial did not show significant improvement in weight loss with GES compared to sham stimulation. The evidence is insufficient to determine the effects of the technology on health outcomes.
Policy
Gastric electrical stimulation is considered investigational for the treatment of gastroparesis of diabetic, idio-
pathic or post-surgical etiology.
Gastric electrical stimulation is considered investigational for the treatment of obesity.

Background
GES, also referred to as gastric pacing, using an implantable device, has been investigated primarily as a treat-
ment for gastroparesis. Currently available devices consist of a pulse generator, which can be programmed to
provide electrical stimulation at different frequencies, connected to intramuscular stomach leads, which are
implanted during laparoscopy or open laparotomy (see Regulatory Status section).

Gastroparesis is a chronic disorder of gastric motility characterized by delayed emptying of a solid meal.
Symptoms include bloating, distension, nausea, and vomiting. When severe and chronic, gastroparesis can be
associated with dehydration, poor nutritional status, and poor glycemic control in diabetic patients. While most
commonly associated with diabetes, gastroparesis is also found in chronic pseudo-obstruction, connective tissue
disorders, Parkinson disease, and psychological pathologic conditions. Some cases may not be associated with
an identifiable cause and are referred to as idiopathic gastroparesis. Treatment of gastroparesis includes pro-
kinetic agents (e.g., metoclopramide) and antiemetic agents (e.g., metoclopramide, granisetron, ondansetron).
Severe cases may require enteral or total parenteral nutrition.

GES has also been investigated as a treatment of obesity. It is used to increase a feeling of satiety with subse-
quent reduction in food intake and weight loss. The exact mechanisms resulting in changes in eating behavior
are uncertain but may be related to neurohormonal modulation and/or stomach muscle stimulation.

Regulatory Status
In 2000, the Gastric Electrical Stimulator (GES) system (now called Enterra™ Therapy System; Medtronic,
Minneapolis, MN) was approved by the U.S. Food and Drug Administration (FDA) through the humanitarian
device exemption process (HDE Approval H990014) for the treatment of gastroparesis. The GES system consists
of four components: the implanted pulse generator, two unipolar intramuscular stomach leads, the stimulator
programmer, and the memory cartridge. With the exception of the intramuscular leads, all other components
have been used in other implantable neurologic stimulators, such as spinal cord or sacral nerve stimulation. The
intramuscular stomach leads are implanted either laparoscopically or during a laparotomy and are connected to
the pulse generator, which is implanted in a subcutaneous pocket. The programmer sets the stimulation para-
meters, which are typically set at an “on” time of 0.1 second alternating with an “off” time of 5.0 seconds.

Currently, no GES devices have been approved by FDA for the treatment of obesity. The Transcend®
(Transneuronix; acquired by Medtronic in 2005), an implantable gastric stimulation device, is available in Europe
for treatment of obesity.

Related Protocol
Vagus Nerve Stimulation

Services that are the subject of a clinical trial do not meet our Technology Assessment Protocol criteria and are
considered investigational. *For explanation of experimental and investigational, please refer to the Technology Assessment Protocol.*

It is expected that only appropriate and medically necessary services will be rendered. We reserve the right to conduct prepayment and postpayment reviews to assess the medical appropriateness of the above-referenced procedures. **Some of this protocol may not pertain to the patients you provide care to, as it may relate to products that are not available in your geographic area.**

**References**

We are not responsible for the continuing viability of web site addresses that may be listed in any references below.