

(70173)

<b>Medical Benefit</b>		<b>Effective Date:</b> 04/01/13	<b>Next Review Date:</b> 11/17
<b>Preauthorization</b>	No	<b>Review Dates:</b> 01/07, 03/08, 03/09, 01/10, 01/11, 01/12, 01/13, 01/14, 11/14, 11/15, 11/16	

**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.*

Populations	Interventions	Comparators	Outcomes
Individuals: • With gastroparesis	Interventions of interest are: • Gastric electrical stimulation	Comparators of interest are: • Conservative management • Medication • Enteral or total parenteral nutrition	Relevant outcomes include: • Symptoms • Treatment-related morbidity
Individuals: • With obesity	Interventions of interest are: • Gastric electrical stimulation	Comparators of interest are: • Conservative management • Medication • Bariatric surgery	Relevant outcomes include: • Change in disease severity • Treatment-related morbidity

**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**

The evidence for the use of GES for treatment of patients with gastroparesis includes three small randomized studies. Relevant outcomes are symptoms and treatment-related morbidity. One randomized study included only 33 patients recruited from 11 centers in the United States. No statistically significant improvement in symptoms was reported for the entire study group compared with placebo, but positive results were reported for the subgroup of 17 patients with diabetic gastroparesis. In the second randomized study of 55 patients, weekly vomiting frequency was significantly lower than baseline values at one-year follow-up, but there was no difference in weekly vomiting frequency between patients who had the device turned on or off during the three-month crossover period. A third study did not demonstrate differences in weekly vomiting frequency between patients who had the device turned on or off during the three-month crossover period. The evidence is insufficient to determine the effects of the technology on health outcomes.

The evidence for the use of GES for treatment of obesity includes one published randomized study (SHAPE trial). Relevant outcomes are change in disease severity (e.g., weight loss) and treatment-related morbidity. This trial

did not show any improvement in weight loss with GES compared with 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, idiopathic 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 treatment 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 that 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 prokinetic agents, such as metoclopramide, and antiemetic agents, such as metoclopramide, granisetron, or ondansetron. Severe cases may require enteral or total parenteral nutrition.

GES has also been investigated as a treatment of obesity as a technique to increase a feeling of satiety with subsequent reduced food intake and weight loss. The exact mechanisms resulting in changes in eating behavior are uncertain but may be related to neuro-hormonal modulation and/or stomach muscle stimulation. There are no GES devices approved by the U.S. Food and Drug Administration for the treatment of obesity. The Transcend® Implantable Gastric Stimulation device, manufactured by Transneuronix and acquired by Medtronic in 2005, is currently available in Europe for treatment of obesity. Medtronic announced in December 2005 that the preliminary results of the Screened Health Assessment and Pacer Evaluation, or SHAPE trial, which was initiated by Transneuronix using the Transcend device, “did not meet the efficacy endpoint of a difference in mean excess weight loss at one year.”

### Regulatory Status

Currently, only the GES system (now called Enterra™ Therapy System; Medtronic, Minneapolis, MN) has been approved by the U.S. Food and Drug Administration (FDA; see note below). 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 parameters, which are typically set at an “on” time of 0.1 second alternating with an “off” time of 5.0 seconds.

**Note:** In March 2000, the GES system was approved by FDA through a humanitarian device exemption (HDE Approval H990014). This regulatory category was established in 1996 and only applies to devices intended to benefit fewer than 4000 patients. The approval process is similar to that of a premarket approval application

(PMA) but is exempt from the effectiveness requirements of a PMA. Thus the application is not required to include results of scientifically valid clinical investigations but must contain sufficient information for FDA to determine that the device does not pose unreasonable or significant risk of illness or injury. A humanitarian use device may only be used in facilities that have an institutional review board to supervise clinical testing of the device.

### Related Protocol

Vagus Nerve Stimulation

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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.

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