MEDICAL POLICY – 7.01.522
Gastric Electrical Stimulation

BCBSA Ref. Policy: 7.01.73
Effective Date: May 1, 2019
Last Revised: April 2, 2019
Replaces: 7.01.73

Related Medical Policies:
1.01.507 Electrical Stimulation Devices
7.01.20 Vagus Nerve Stimulation
7.01.150 Vagus Nerve Blocking Therapy for Treatment of Obesity

Select a hyperlink below to be directed to that section.

Policy Criteria | Documentation Requirements | Coding
Related Information | Evidence Review | References | History

∞ Clicking this icon returns you to the hyperlinks menu above.

Introduction

Gastroparesis is a condition in which the normal movement of food from the stomach to the small intestine is drastically slowed or has stopped. This can lead to nausea and vomiting. Gastric electrical stimulation (GES) is a treatment that sends weak electrical signals to the nerves and smooth muscles in the lower stomach. This treatment helps decrease nausea and vomiting caused by gastroparesis. A small battery-powered device is surgically placed in the skin in the lower belly area. Wires are then placed in the area to be stimulated. This policy discusses when GES may be considered medically necessary. It has also been proposed as a treatment for obesity. The one published medical study that looked at using GES for obesity did not show it improved weight loss. GES for the treatment of obesity is considered investigational (unproven) because more medical studies are needed.

Note: The Introduction section is for your general knowledge and is not to be taken as policy coverage criteria. The rest of the policy uses specific words and concepts familiar to medical professionals. It is intended for providers. A provider can be a person, such as a doctor, nurse, psychologist, or dentist. A provider also can be a place where medical care is given, like a hospital, clinic, or lab. This policy informs them about when a service may be covered.
Policy Coverage Criteria

Service | Medical Necessity
--- | ---
Gastric electrical stimulation | Gastric electrical stimulation may be considered medically necessary in the treatment of chronic, intractable nausea and vomiting secondary to gastroparesis of diabetic or idiopathic etiology when ALL of the following criteria are met:
- Significantly delayed gastric emptying as documented by standard scintigraphic imaging of solid food
  AND
- Patient is refractory or intolerant of prokinetic medications and antiemetic medications
  AND
- Patient’s nutritional status is sufficiently low that total parenteral nutrition is likely to become medically necessary

Gastric electrical stimulation is investigational for the treatment of obesity and all other indications.

Documentation Requirements

The medical records submitted for review should document that medical necessity criteria are met. The record should include clinical documentation of ALL of the following:
- Member has chronic, intractable nausea and vomiting secondary to gastroparesis (inability to empty food) caused by diabetes or for an unknown reason
- Significantly delayed gastric emptying confirmed by standard scintigraphic imaging (gastric emptying scan) of solid food
- Member has not responded or is intolerant to the use of prokinetic (antireflux) and antiemetic (antinausea and vomiting) medications
- The need for parenteral nutrition is likely to become medically necessary because of member’s inadequate nutritional status

Note: Vagus nerve stimulation is addressed in a separate medical policy. See Related Policies.
<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
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<tr>
<td>CPT</td>
<td></td>
</tr>
<tr>
<td>43647</td>
<td>Laparoscopy, surgical; implantation or replacement of gastric neurostimulator electrodes, antrum</td>
</tr>
<tr>
<td>43648</td>
<td>Laparoscopy, surgical; revision or removal of gastric neurostimulator electrodes, antrum</td>
</tr>
<tr>
<td>43881</td>
<td>Implantation or replacement of gastric neurostimulator electrodes, antrum, open</td>
</tr>
<tr>
<td>43882</td>
<td>Revision or removal of gastric neurostimulator electrodes, antrum, open</td>
</tr>
<tr>
<td>HCPCS</td>
<td></td>
</tr>
<tr>
<td>E0765</td>
<td>FDA approved nerve stimulator, with replaceable batteries, for treatment of nausea and vomiting</td>
</tr>
<tr>
<td>L8680</td>
<td>Implantable neurostimulator electrode, each</td>
</tr>
<tr>
<td>L8685</td>
<td>Implantable neurostimulator pulse generator, single array, rechargeable, includes extension</td>
</tr>
<tr>
<td>L8686</td>
<td>Implantable neurostimulator pulse generator, single array, nonrechargeable, includes extension</td>
</tr>
<tr>
<td>L8687</td>
<td>Implantable neurostimulator pulse generator, dual array, rechargeable, includes extension</td>
</tr>
<tr>
<td>L8688</td>
<td>Implantable neurostimulator pulse generator, dual array, nonrechargeable, includes extension</td>
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**Related Information**

N/A

**Evidence Review**
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.

Background

Gastroparesis

Gastroparesis is a chronic disorder of gastric motility characterized by delayed emptying of a solid meal from the stomach. 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 (eg, metoclopramide) and antiemetic agents (eg, metoclopramide, granisetron, or ondansetron). Severe cases may require enteral or total parenteral nutrition.

Treatment

Gastric electrical stimulation (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. The pulse generator is connected to intramuscular stomach leads, which are implanted during laparoscopy or open laparotomy (see Regulatory Status section).

Obesity

GES has also been investigated as a treatment of obesity. It is used to increase a feeling of satiety with subsequent 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.

**Summary of Evidence**

For individuals who have gastroparesis who receive gastric electrical stimulation (GES), the evidence includes randomized controlled trials (RCTs), nonrandomized studies, and systematic reviews. Relevant outcomes are symptoms and treatment-related morbidity. Five crossover RCTs have been published. A 2017 meta-analysis of these 5 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.

A Hayes Medical Technology Directory report analyzed the evidence (n=10 studies) for GES for the treatment of gastroparesis. The report evaluated controlled studies (n=7 studies/18-241 patients) and uncontrolled studies (n=3 studies/131-233 patients). The controlled trials included RCTs (n=3 studies), prospective (n=2), and retrospective studies (n=2). Patients were selected who had symptomatic gastroparesis refractory to medical treatment with diagnoses of diabetic gastric neuropathy or idiopathic gastroparesis. Exclusion criteria included the structural cause of symptoms, psychogenic vomiting, chemical dependency, previous gastric surgery, and pregnancy. Outcomes measured were gastroparesis symptom severity and gastric retention assessed by scintigraphy. Additional outcomes included the need for nutritional support, and changes in antiemetic and/or prokinetic medications. Follow-up timeframe varied among studies, the longest follow-up being four years. The report found poor to fair quality evidence indicating that GES may improve gastroparesis symptoms and gastric emptying as well as decrease the need for nutritional support in some patients with refractory gastroparesis. Overall, GES was found to be safe with the device removal rate ranging from 7%-12% in most studies, primarily due to lack of symptom improvement. It was noted that despite the low quality of the supportive evidence, GES may be an option for patients with debilitating gastroparesis that is refractory to medical treatment (Hayes, 2016 update).

Overall, the evidence for gastric electrical stimulation is not very strong. However, this policy requires that the patient has tried and failed other treatments and that their nutritional status is so depleted that total parenteral nutrition (TPN) may soon become medically necessary. TPN is invasive and not without its own risks. Therefore, even though the evidence for gastric electrical stimulation is not strong and the Enterra Therapy System had only been approved by the FDA
under a Humanitarian Device Exemption (HDE), GES may be helpful and allow the patient to avoid the risks associated with receiving ongoing TPN.

For individuals who have obesity who receive GES, the evidence includes an 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.

Ongoing and Unpublished Clinical Trials

Some currently unpublished trials that might influence this review are listed in Table 1.

Table 1. Summary of Key Trials

<table>
<thead>
<tr>
<th>NCT No.</th>
<th>Trial Name</th>
<th>Planned Enrollment</th>
<th>Completion Date</th>
</tr>
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<tbody>
<tr>
<td><strong>Ongoing</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>NCT03261531</td>
<td>Dermatome Electrical Stimulation on Individuals With Overweight and Class I Obesity</td>
<td>16</td>
<td>Dec 2019</td>
</tr>
</tbody>
</table>

NCT: national clinical trial.
* Denotes industry-sponsored or cosponsored trial.

Clinical Input Received from Physician Specialty Societies and Academic Medical Centers

While the various physician specialty societies and academic medical centers may collaborate with and make recommendations during this process, through the provision of appropriate reviewers, input received does not represent an endorsement or position statement by the physician specialty societies or academic medical centers, unless otherwise noted.

2015 Input

In response to requests, input was received from 1 specialty society (2 reviewers) and 4 academic centers while this policy was under review in 2015. Most respondents agreed that
gastric electrical stimulation (GES) should be considered investigational for gastroparesis. There was a lack of consensus whether GES should be considered medically necessary for any specific indication (eg, diabetic gastroparesis, idiopathic gastroparesis, gastroparesis of postsurgical etiology). The reviewers were not asked about GES for treatment of obesity.

**2009 Input**

In response to requests, input was received from 4 academic medical centers (5 reviewers) while this policy was under review in 2009. There was strong agreement among reviewers about the limited data for use of GES in diabetic and idiopathic gastroparesis and about the need for randomized controlled trials. There was strong agreement that GES is investigational in the treatment of obesity.

**Practice Guidelines and Position Statements**

*National Institute for Health and Care Excellence*

The National Institute for Health and Care Excellence (2014) has issued guidance on gastroelectrical stimulation for gastroparesis. The Institute made the following recommendations:

1. “Current evidence on the efficacy and safety of gastric electrical stimulation for gastroparesis is adequate to support the use of this procedure with normal arrangements for clinical governance, consent, and audit.

2. ... clinicians should inform patients considering gastric electrical stimulation for gastroparesis that some patients do not get any benefit from it. They should also give patients detailed written information about the risk of complications, which can be serious, including the need to remove the device.

3. Patient selection and follow-up should be done in specialist gastroenterology units with expertise in gastrointestinal motility disorders, and the procedure should only be performed by surgeons working in these units.”
**American College of Gastroenterology**

The American College of Gastroenterology published practice guidelines on management of gastroparesis in 2013.\(^\text{18}\) The College recommended that:

GES [gastric electrical stimulation] may be considered for compassionate treatment in patients with refractory symptoms, particularly nausea and vomiting. Symptom severity and gastric emptying have been shown to improve in patients with DG [diabetic gastroparesis], but not in patients with IG [idiopathic gastroparesis] or PSG [postsurgical gastroparesis].

[Conditional recommendation (there is uncertainty about trade-offs), moderate level of evidence (further research would be likely to have an impact on the confidence in the estimate of effect).]

**Medicare National Coverage**

There is no national coverage determination.

**Regulatory Status**

In 2000, the Gastric Electrical Stimulator system (now called Enterra™ Therapy System; Medtronic) was approved by the U.S. Food and Drug Administration through the humanitarian device exemption process (H990014) for the treatment of gastroparesis. The GES system consists of 4 components: the implanted pulse generator, 2 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.

Currently, no GES devices have been approved by the Food and Drug Administration 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.

**References**
<table>
<thead>
<tr>
<th>Date</th>
<th>Comments</th>
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<tr>
<td>01/18/01</td>
<td>Add to Surgery Section - New Policy</td>
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<td>03/11/03</td>
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<td>05/11/04</td>
<td>Replace Policy - Policy revised; no change in policy statement; new HCPC code added.</td>
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<td>06/08/04</td>
<td>Replace Policy - Policy replaces BC.7.01.73 due to policy statement being changed from investigational to medically necessary.</td>
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<tr>
<td>09/01/04</td>
<td>Replace Policy - Policy renumbered from PR.7.01.122. No changes to dates.</td>
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<tr>
<td>01/11/05</td>
<td>Replace Policy - BCBSA update, scheduled review date changed. Policy statement adds obesity as investigational.</td>
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<td>06/16/05</td>
<td>Device name change added - Reference to Enterra added to Gastric Electrical Stimulation System for clarification purposes only. MPC approval not needed.</td>
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<td>02/09/10</td>
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<td>08/20/12</td>
<td>Replace Policy, Policy updated with literature review, references 21 and 22 added; no change in policy statement.</td>
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<td>02/04/13</td>
<td>Code update. HCPCS code E0765 added to the policy.</td>
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<td>02/12/13</td>
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<td>Replace policy. Policy updated with extensive literature revision. No change in policy statement. CPT codes 0155T, 0156T, 0157T and 0158T removed from policy; they were deleted effective 1/2012.</td>
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<td>12/03/13</td>
<td>Coding Update. Add ICD-10 codes.</td>
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<td>Interim Update. Adding FDA Approved device. Related policy 7.01.20 added.</td>
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<td>09/01/15</td>
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<td>01/10/17</td>
<td>Interim review. Coding update; added CPT code 95980. Combined coding tables.</td>
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<td>Annual review, changes approved April 11, 2017. Policy updated with literature review through December 22, 2016; reference 1 added. Policy statements unchanged.</td>
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<td>08/25/17</td>
<td>Coding update, removed CPT code 95980. Supporting information added to Summary of Evidence section. Policy moved into new format; no change to policy statements.</td>
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<td>05/01/18</td>
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<tr>
<td>05/01/19</td>
<td>Annual Review, approved April 2, 2019. Policy updated with literature review through January 2019; references 8-9 added. Policy statements unchanged.</td>
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U.S. Department of Health and Human Services
200 Independence Avenue SW, Room S09F, HHH Building
Washington, D.C. 20201, 1-800-368-1019, 800-537-7697 (TDD)

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037338 (07-2016)
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