Medical Policy

Gastric Electrical Stimulation

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Policy Number: 636
BCBSA Reference Number: 7.01.73
NCD/LCD: N/A

Related Policies
- Vagus Nerve Stimulation, #474
- Vagal Nerve Blocking Therapy for Treatment of Obesity, #644

Policy

Commercial Members: Managed Care (HMO and POS), PPO, and Indemnity
Medicare HMO BlueSM and Medicare PPO BlueSM Members

Gastric electrical stimulation is considered INVESTIGATIONAL for the treatment of gastroparesis of diabetic or idiopathic etiology.

Gastric electrical stimulation is considered INVESTIGATIONAL for the treatment of obesity.

Prior Authorization Information

Pre-service approval is required for all inpatient services for all products.
See below for situations where prior authorization may be required or may not be required for outpatient services.
Yes indicates that prior authorization is required.
No indicates that prior authorization is not required.
N/A indicates that this service is primarily performed in an inpatient setting.

<table>
<thead>
<tr>
<th>Outpatient</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Commercial Managed Care (HMO and POS)</td>
<td>This is not a covered service.</td>
</tr>
<tr>
<td>Commercial PPO and Indemnity</td>
<td>This is not a covered service.</td>
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<tr>
<td>Medicare HMO BlueSM</td>
<td>This is not a covered service.</td>
</tr>
<tr>
<td>Medicare PPO BlueSM</td>
<td>This is not a covered service.</td>
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</tbody>
</table>
CPT Codes / HCPCS Codes / ICD Codes

Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement. Please refer to the member’s contract benefits in effect at the time of service to determine coverage or non-coverage as it applies to an individual member.

Providers should report all services using the most up-to-date industry-standard procedure, revenue, and diagnosis codes, including modifiers where applicable.

The following codes are included below for informational purposes only; this is not an all-inclusive list.

The following CPT codes are considered investigational for Commercial Members: Managed Care (HMO and POS), PPO, Indemnity, Medicare HMO Blue and Medicare PPO Blue:

<table>
<thead>
<tr>
<th>CPT Codes</th>
<th>Code Description</th>
</tr>
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<tbody>
<tr>
<td>43647</td>
<td>Laparoscopy, surgical; implantation or replacement 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>64590</td>
<td>Insertion or replacement of peripheral or gastric neurostimulator pulse generator or receiver, direct, or inductive coupling</td>
</tr>
<tr>
<td>95980</td>
<td>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, with programming</td>
</tr>
<tr>
<td>95981</td>
<td>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</td>
</tr>
<tr>
<td>95982</td>
<td>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, with reprogramming</td>
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Description

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, connected to intramuscular stomach leads that are implanted during laparoscopy or open laparotomy.

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 pseudoobstruction, 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.”

**Summary**

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.

The evidence for the use of GES for treatment of patients with gastroparesis includes 3 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 1-year follow-up, but there was no difference in weekly vomiting frequency between patients who had the device turned on or off during the 3-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 3-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 1 published randomized study (SHAPE trial). Relevant outcomes are change in disease severity (eg, 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 History**

<table>
<thead>
<tr>
<th>Date</th>
<th>Action</th>
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<tbody>
<tr>
<td>3/2017</td>
<td>New references added from BCBSA National medical policy.</td>
</tr>
<tr>
<td>2/2016</td>
<td>New references added from BCBSA National medical policy.</td>
</tr>
<tr>
<td>12/2015</td>
<td>Clarified coding information.</td>
</tr>
<tr>
<td>10/2014</td>
<td>New references added from BCBSA National medical policy.</td>
</tr>
<tr>
<td>6/2014</td>
<td>Updated Coding section with ICD10 procedure and diagnosis codes, effective 10/2015.</td>
</tr>
<tr>
<td>12/2013</td>
<td>New references from BCBSA National medical policy. Removed HCPCS codes L8680 and L8685-L8686 as they do not meet the intent of the policy.</td>
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<tr>
<td>10/2013</td>
<td>Removed CPT codes 43648, 43882 and 64595 as they do not apply to the policy.</td>
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</tbody>
</table>
No changes to policy statements.

No changes to policy statements.

4/2008 BCBSA National medical policy review.
No changes to policy statements.

No changes to policy statements.

No changes to policy statements.

1/2007 BCBSA National medical policy review.
No changes to policy statements.

Information Pertaining to All Blue Cross Blue Shield Medical Policies
Click on any of the following terms to access the relevant information:
Medical Policy Terms of Use
Managed Care Guidelines
Indemnity/PPO Guidelines
Clinical Exception Process
Medical Technology Assessment Guidelines

References