# Clinical Policy: Gastric Electrical Stimulation

Reference Number: LA.CP.MP.40
Date of Last Revision: ~~03/24~~03/24

Coding Implications
Revision Log

**See Important Reminder at the end of this policy for important regulatory and legal information.**

**Description**

Gastric electrical stimulation (GES) has been used as compassionate care in patients who are proven refractory to conventional treatment for gastroparesis.[1] It can be used as an alternative to surgery to reduce symptoms of gastroparesis.[2] The GES device includes a pair of leads that are placed in the muscularis propria of greater curvature of the stomach about ten cm proximal to the pylorus.[3] The leads are connected to a pulse generator that is typically placed subcutaneously in the right or left upper quadrants of the abdomen, and an external programming device controls the gastric stimulation parameters of the GES device.[3] This stimulation has not shown a significant improvement in gastric emptying but has proven to be beneficial in those who have nausea and vomiting as primary symptoms.[~~4,5~~ 8,10]

**Policy/Criteria**

**I.** It is the policy of Louisiana Healthcare Connections that gastric electrical stimulation (GES) is **medically necessary** for diabetic and idiopathic gastroparesis when all ~~of~~ the following criteria are met:

A. Member/enrollee is ≥ 18 years of age;

~~A.~~B. Diagnosis of diabetic or idiopathic gastroparesis confirmed by gastric emptying scintigraphy;

~~B.~~C. Severe nausea and vomiting occurring at least once daily on most days of the week for the duration of ~~-~~more than one year;

~~C.~~D. Documented intolerance or failure of a trial of antiemetic, dietary modifications, and prokinetic drug therapy;

~~D.~~E. Not currently pregnant;

~~E.~~F. Technology is provided in accordance with the Humanitarian Device Exemption (HDE) specifications of the U.S. Food and Drug Administration (FDA).

*Note:*

- Current recommended combination prokinetic therapy includes metoclopramide and erythromycin, and centrally acting antidepressants used as symptom modulators.
- A humanitarian device exemption (HDE) is granted by the FDA. A humanitarian use device (HUD) is a device that is intended to benefit patients in the treatment or diagnosis of a disease or condition that affects fewer than 8,000 individuals in the United States annually. A HUD may only be used in facilities that have established a local institutional review board to supervise clinical testing of devices and after an independent review board has approved the use of the device to treat or diagnose the specific disease.[~~14~~11]

**II.** It is the policy of Louisiana Healthcare Connections that GES is **not medically necessary** for the reduction of pain, fullness, bloating, or acid reflux symptoms as there is no evidence to support efficacy of such therapy.

**III.** It is the policy of Louisiana Healthcare Connections that current evidence in peer-reviewed literature does not support the use of GES for any other indications, including, but not limited to the treatment of obesity.

**Background**

*Gastric Electrical Stimulation (GES) for Gastroparesis*

Gastroparesis is a disorder in which there is delayed gastric emptying following ingestion of food~~,~~ in the absence of mechanical obstruction due to abnormal or absent motility of the stomach.[~~2,6,7~~ 4,5] The stomach is unable to contract normally and cannot crush food or propel food into the small intestine properly.[~~2,8~~ 6]

There are numerous conditions associated with gastroparesis, but the majority of gastroparesis cases are either idiopathic or associated with diabetes.[4,~~6,8~~] The main symptoms of gastroparesis include nausea, vomiting, early satiety, bloating, and abdominal discomfort.[4,~~6,8~~] Nausea and vomiting may be so severe that it causes weight loss, dehydration, electrolyte disturbances, and malnutrition.[3]

It is theorized that GES works in the following ways:

1. Activation of the central mechanisms for nausea and vomiting control related to afferent nerves being stimulated by the constant high frequency current in the stomach wall~~.~~;
2. Enhanced relaxation of the fundus of the stomach by the electrical current, thus providing better accommodation and decreased sensitivity to distention;
3. Augmentation of the amplitude of gastric slow wave after eating;
4. Increase in cholinergic function and decreased sympathetic functions;
5. Small and unpredictable improvements in gastric emptying.

Multiple studies on GES for gastroparesis have shown an improvement in quality ~~-~~of~~-~~life scores, even though on average, gastric emptying did not change. Quality of life scores improved along with weight gain, and there was a reduction in hemoglobin A1C (HbA1c) and a decrease in hospitalizations.[~~5~~8] Nausea and vomiting also improved for at least one year after surgery.[~~4,5,9~~ 8,11]

*Gastric Electrical Stimulation for Obesity*

GES is currently not supported by peer-reviewed literature as a treatment for obesity. Cha et ~~al~~[~~10~~]al[7] reviewed current approaches to evaluate the effect of GES on obesity and included 31 studies in their systematic review. Most of the studies showed weight loss during the first 12 months of treatment, but only a few studies performed follow-up past one year. Some of the evaluated GES treatments also showed positive effects in lowering HbA1c and blood pressure. The review concluded that GES is promising for the treatment of obesity, but stronger studies with longer follow-up are needed to determine long-term effects[~~10~~ 7]

~~Lebovitz~~[~~11~~]Lebovitz[8] reviewed the evidence on three different methods of GES, including the Transcend® Implantable Gastric Stimulator, the Maestro™ vagal blockade device, and the DIAMOND™ gastric electrical stimulatory device. Two randomized controlled trials failed to show a significant benefit in excess weight loss with the Transcend device. The other evaluated GES device, the DIAMOND, has been assessed in clinical trials with obese patients with type II-

diabetes. Findings were positive and included reduced HbA1c and weight loss, but these results varied among patients included in the treatment and seemed to be influenced by baseline HbA1c levels and triglyceride levels. Further research is needed to determine long-term effects and appropriate patient selection criteria to ensure the best outcomes.[11] [8]

**Coding Implications**

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NOTE: Coverage is subject to each requested code's inclusion on the corresponding LDH fee schedule. Non-covered codes are denoted (*) and are reviewed for Medical Necessity for members under 21 years of age on a per case basis.

| CPT® Codes | Description |
|---|---|
| 43647* | Laparoscopy, surgical; implantation or replacement of gastric neurostimulator electrodes, antrum |
| 43648* | Laparoscopy, surgical; revision or removal of gastric neurostimulator electrodes, antrum |
| 43881* | Implantation or replacement of gastric neurostimulator electrodes, antrum, open |
| 43882* | Revision or removal of gastric neurostimulator electrodes, antrum, open |
| 64590 | Insertion or replacement of peripheral, sacral, or gastric neurostimulator pulse generator or receiver, ~~direct~~requiring pocket creation and connection between electrode array and pulse generator or ~~inductive coupling~~ receiver |
| 64595* | Revision or removal of peripheral, sacral, or gastric neurostimulator pulse generator or receiver, with detachable connection to electrode array |
| 95980* | Electronic analysis of implanted neurostimulator pulse generator system (eg, 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 |
| 95981* | Electronic analysis of implanted neurostimulator pulse generator system (eg, 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 |
| 95982* | Electronic analysis of implanted neurostimulator pulse generator system (eg, 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 |

~~* All non-covered codes are reviewed for medical necessity for members under 21 years old~~

| HCPCS Codes | Description |
|---|---|

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|---|---|
| C1767 | Generator, neurostimulator (implantable), ~~nonrechargeable~~non-rechargeable |
| C1778 | Lead, neurostimulator (implantable) |

| HCPCS Codes | Description |
|---|---|
| L8679* | Implantable neurostimulator, pulse generator, any type |
| L8680~~*~~ | Implantable neurostimulator electrode, each |
| L8688~~*~~ | Implantable neurostimulator pulse generator, dual array, ~~nonrechargeable~~non-rechargeable, includes extension |

~~* All non-covered codes are reviewed for medical necessity for members under 21 years old~~

| Reviews, Revisions, and Approvals | Revision Date | Approval Date |
|---|---|---|
| Converted corporate to local policy. | 08/15/2020 | |
| Annual review. References reviewed and updated. Updated description and background with no clinical significance. Added "and may not support medical necessity" to Coding Implications section | 5/22 | |
| Annual review. Updated description with no impact on criteria. Added criteria that gastroparesis should be confirmed by scintigraphy. Modified criteria in I.B requiring daily vomiting to say that vomiting should happen at least once daily on most days of the week. "Dietary modifications" added to I.C. and "FDA specifications" added as I.E. Updated verbiage in note at the end of criteria I. and added additional note about humanitarian device exemptions. ICD-10 code table removed. References reviewed and updated. External specialist reviewed. | 4/23 | 7/21/23 |

| | | |
|---|---|---|
| Annual review. Updated description and background with no clinical significance. Added I.A. "Member/enrollee is ≥ 18 years of age". Updated I.B. to include "diabetic or" in describing type of gastroparesis. Updates made to CPT code descriptions. References reviewed and updated. | 03/24 | |

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**Important Reminder**

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